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BMJ Open Downsides of face masks and possible mitigation strategies: a systematic review and meta-analysis

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ABSTRACT

Objective To identify, appraise and synthesise studies evaluating the downsides of wearing face masks in any setting. We also discuss potential strategies to mitigate these downsides.

Design Systematic review and meta-analysis.

Data sources PubMed, Embase, CENTRAL and EuropePMC were searched (inception–18 May 2020), and clinical registries were searched via CENTRAL. We also did a forward–backward citation search of the included studies.

Inclusion criteria We included randomised controlled trials and observational studies comparing face mask use to any active intervention or to control.

Data extraction and analysis Two author pairs independently screened articles for inclusion, extracted data and assessed the quality of included studies. The primary outcomes were compliance, discomforts, harms and adverse events of wearing face masks.

Results We screened 5471 articles, including 37 (40 references); 11 were meta-analysed. For mask wear adherence, 47% (95% CI 25% to 68%, $p<0.0001$), more people wore face masks in the face mask group compared with control; adherence was significantly higher (26%, 95% CI 8% to 46%, $p<0.01$) in the surgical/medical mask group than in N95/P2 group. The largest number of studies reported on the discomfort and irritation outcome (20 studies); fewest reported on the misuse of masks, and none reported on mask contamination or risk compensation behaviour. Risk of bias was generally high for blinding of participants and personnel and low for attrition and reporting biases.

Conclusions There are insufficient data to quantify all of the adverse effects that might reduce the acceptability, adherence and effectiveness of face masks. New research on face masks should assess and report the harms and downsides. Urgent research is also needed on methods and designs to mitigate the downsides of face mask wearing, particularly the assessment of possible alternatives.

Systematic review registration Open Science Framework website <https://osf.io/sa6kf/> (timestamp 20-05-2020).

INTRODUCTION

Respiratory viruses are predominantly transmitted by aerosol, droplets and fomites.¹ Face

Strengths and limitations of this study

- This is the first systematic review to investigate the downsides of wearing face masks.
- We included non-randomised study designs in addition to randomised controlled trials, as trials frequently under-reported or failed to report harms.
- We reported two deviations from the study protocol, relating to the measurement of effect and the subgroup analysis.

masks—such as surgical masks, N95 masks and face shields, and substitutes for surgical masks such as home-made cloth masks—are a physical barrier to aerosol and droplet transmission. During the COVID-19 pandemic, some jurisdictions have implemented policies mandating the use of masks in public places, on public transport or in other crowded environments to prevent people becoming infected or infecting others.

While most health organisations mandate the use of face masks by health workers when caring for patients during a pandemic, recommendations for mask wear in the community vary widely and include: use by all, use only in certain situations (eg, on public transport or in crowded places where social distancing is not possible), and no specific recommendations about mask use.

Several trials have evaluated the impact on respiratory infections by use of surgical and N95 masks, which may, at best, modestly reduce acute respiratory infection transmission.^{2–4} Population observational studies suggest that masks have a more substantial effect.⁵ However, the downsides of mask-wearing were either not considered or not reported in most studies. Most trials have focused on face masks protecting the wearer, rather than others in the community, are often low powered, and include confounding factors resulting in the current

evidence for the efficacy of face masks being less than adequate.⁶

The current controversies, mixed messaging and debate over the use of face masks to prevent the spread of COVID-19 warrants further investigation into their use. Anecdotal evidence, and some studies, suggest that there may be a variety of downsides arising from mask use, including: discomfort, sense of difficulty breathing and communication problems particularly for those who use lip reading.^{6,7} Our aim is to systematically identify and summarise these downsides to assist policymakers when formulating mask-wearing policies in public settings. We also discuss potential strategies to mitigate downsides of mask-wearing.

METHODS

This systematic review is reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.⁸ We followed the '2 week systematic review' processes for the review.⁹ The review protocol was developed prospectively and uploaded to the Open Science Framework data on 20 May 2020 (see: <https://osf.io/sa6kf/>). Deviations from the protocol are reported in the Methods section and highlighted as a limitation in the Discussion section.

Inclusion criteria

We included studies of people of any age or gender, in any setting. We included studies of any face covering aimed at reducing virus transmission, including surgical masks, N95 masks, cloth masks (both homemade and commercially available) (see online supplemental appendix 1 for a summary of included face masks and their intended purpose). Studies evaluating the use of masks for non-virus transmission purposes (eg, valved masks for preventing inhalation of airborne contaminants such as particles, gases or vapours) were excluded (see online supplemental appendix 2 for a complete list of excluded face masks).

We included studies comparing the use of face mask to any active intervention (eg, another mask or another intervention such as hand washing) and studies comparing the use of face mask to control (comprising standard practice, ie, face masks not explicitly provided to study group) in situations where their use was not mandatory.

We included only primary studies, that is, randomised controlled trials (RCTs) and observational studies of any design. We intentionally included this range of study types to identify appropriate data that corresponded with the listed outcomes. For example, surveys are appropriate for identifying frequency of discomfort, and breathing trials are appropriate for understanding physiological changes. We excluded studies that could not provide a quantitative estimate of the size or frequency of adverse effects such as case reports, case series, as well as qualitative studies, and reviews.

Box 1 List of extracted information

- ▶ **General information:** study authors, location, study design, duration, aim and setting.
- ▶ **Participants:** health status, disease (if applicable), sample size, age, gender, smoker status and comorbidities.
- ▶ **Intervention and comparator(s):** number of participants, type of face covering, adjunct interventions, number of face coverings used, duration of use and disposal.
- ▶ **Outcomes:** definition, measurement instrument, number of adverse events or harms reported (the outcomes were discomforts, harms and adverse events of wearing face masks, adherence to face mask wearing, misuse of masks, discomfort and other physical irritation from masks, psychological outcomes (eg, fear), dyspnoea (difficulty breathing and shortness of breath) and other physiological impacts, communication impacts and mask contamination).

Search strategies

We searched PubMed, Embase, Cochrane CENTRAL, EuropePMC (inception–18 May 2020). The search string was designed for PubMed and translated for use in other databases using the Polyglot Search Translator (online supplemental appendix 3).¹⁰ Clinical trial registries were searched via Cochrane CENTRAL, which includes the WHO International Clinical Trials Registry Platform (ICTRP) and clinicaltrials.gov. On 22 May 2020, we conducted a backwards and forwards citation analysis in Scopus, on all of the included studies.

No restrictions by language or publication date were imposed. We included publications that were published in full; abstract-only publications were included if they had an accompanying record (eg, trial registry record or another public report), with additional information.

Study selection and screening

Two author pairs (MB and NK, AMS and JC) independently screened the titles and abstracts against the inclusion criteria. One author (JC) retrieved full text, and two author pairs (MB and NK, AMS and JC) screened the full texts. Disagreements were resolved by discussion or a third author (PG or CDM).

Data extraction

A data extraction form was piloted on three studies. Two author pairs (MB and NK, AMS and JC) extracted the data (see [box 1](#)).

Assessment of risk of bias in included studies

Two author pairs (MB and NK, AMS and JC) independently assessed the risk of bias using the Cochrane Risk of Bias Tool.¹¹ Disagreements were resolved by discussion or a third author (CDM or PG). Each potential source of bias was graded as low, high or unclear, and judgements were supported by a quote from the study.

Measurement of effect and data synthesis

Where feasible (≥ 2 studies reporting the same outcome), we expressed outcome measures as odds ratios (ORs) with 95% CIs, analysed using Review Manager (RevMan

V.5). Anticipating considerable heterogeneity among the included studies, we used a random effects model. We reported the adherence to face mask wear using risk difference (RD) rather than OR to more clearly convey the differences in adherence between the intervention and control group (not prespecified in the protocol).

When meta-analysis was not possible or appropriate, we followed the guidance of the Cochrane Collaboration (Cochrane Handbook Section 12.2).¹¹ When narrative synthesis was required, we reported the results separately for each harm or adverse outcome.

The individual was used as the unit of analysis, where possible; otherwise, we extracted the information as it was presented, for example, the number of harms in each group. We attempted to contact investigators or study sponsors to provide missing data.

We used the I^2 statistic to measure heterogeneity. Because we included fewer than 10 trials, we did not create a funnel plot.

We did not prespecify subgroup or sensitivity analyses. However, as data were available, we conducted a subgroup analysis of adherence to mask-wearing by studies that evaluated face mask wear alone and those evaluating face mask together with hand washing.

Patient and public involvement

Patients and the public were not involved in the design and conduct of this review.

RESULTS

Database searches identified 4691 publications, supplemented with 2035 references from forward and backward citation searches and other sources, totalling 6726. After deduplication, 5471 references were screened by title and abstract; we full-text screened 214 references, excluding 174 (see online supplemental appendix 4 for a list of excluded studies with reasons). We included 40 articles^{12–51} corresponding to 37 studies (table 1 reports the characteristics of included studies) and meta-analysed 11 studies.^{15 21 22 26 31–34 41 45 47} (figure 1).

Risk of bias

Inclusion of both observational studies and RCTs could explain the high risk of bias across the included studies. Reporting of sequence generation, allocation concealment and blinding of outcome assessment was poor in 20%–30% of studies. Due to the nature of interventions, blinding of participants was rare. For RCTs, we reported blinding of outcome assessment for the main trial (not the adverse events), as some outcomes were lab confirmed and were considered of low risk. We found no evidence of incomplete outcome data or selective reporting of outcomes. Funding statement, funder's role and authors' conflict of interests were adequately reported in most studies (see figure 2, and figure 3 in online supplemental appendix 5).

Adherence to face mask wearing

Seventeen studies (14 RCTs, 3 observational)^{10 13 17} reported on adherence to face mask wearing; of these 11 studies had sufficient data to pool and were meta-analysed.

Face mask versus control comparison

Comparison of face masks with control was subgrouped into studies comparing face mask alone versus control and studies of face mask plus hand washing versus control (figure 3).

Face masks alone versus control (five studies) showed the face mask group had a significantly higher face mask wear compared with control (RD: 0.46, 95% CI 0.24 to 0.67, $p<0.0001$). Studies evaluating face mask plus hand washing versus control ($n=3$) similarly showed significantly higher face mask wear in the face mask group (RD: 0.47 (95% CI 0.07 to 0.88, $p<0.0001$).

Overall, seven studies (3303 participants) compared face masks with control. Face mask wear was 47% higher in the face mask group, although heterogeneity was very high (RD: 0.47, 95% CI 0.25 to 0.68, $p<0.0001$, $I^2=98\%$).

We explored the possible sources of heterogeneity. Excluding studies with three or more domains at high risk of bias did not decrease heterogeneity ($I^2=96\%$ for face mask vs control; 99% for face mask plus hand washing vs control) (figure 4, online supplemental appendix 5). We excluded study population as the source of heterogeneity, because subgrouping studies by those in a community/household settings (which included both index cases and their contacts) versus those in a hospital setting (which included healthy healthcare workers) likewise did not decrease heterogeneity ($I^2=99\%$ for community/household studies, and 97% for hospital studies) (figure 5, online supplemental appendix 5). We excluded intervention and control as sources of heterogeneity, since all studies compared medical/surgical masks to control (no mask), although some mask-wear did occur in the control groups.

We consider the outcome measurement to be the most likely other source of heterogeneity. All studies relied on self-reporting of the outcome; only one verified this by counting the number of masks used.²¹ What was considered 'wearing a face mask' varied: it was unclear,^{15 21 45} involved wearing a face mask 'always or mostly/often',^{22 47} included wearing a face mask while on hospital property, performing a healthcare worker role²⁶ and included face mask wear during a shift for 70% of time or more.³² The follow-up was very short (5–9 days) for four studies^{15 21 22 47}; it was longer for three studies (21–77 days).^{26 32 45}

Face mask (surgical/medical) versus face mask (N92/P2 mask)

Four studies (7960 participants) compared adherence for different face masks.^{31 33 34 41} Face mask wear was significantly higher in the surgical/medical face mask group than in the N95/P2 group, OR=1.26 (95% CI 1.08 to 1.46, $p<0.01$). Heterogeneity was very low ($I^2=27\%$) (figure 4).

Table 1 Characteristics of included studies

First author (country, year)	Study design	Setting	Study duration	Type of participants				Type of face mask intervention†				Type of reported outcomes (adverse effects) analysed							
				Healthy		Sick*		Number of participants	Surgical	N95	Any	Other	Discomfort and irritation	Dyspnoea and other physiological	Misuse	Adherence	Psychological impacts	Communication impacts	Mask contamination
				A	Ch	A	Ch												
Aiello ¹² (USA, 2012)	C-RCT	RH	3M	✓				1188; 37 RH	✓			✓							
Allison ¹³ (USA, 2010)	Single-arm study	Sch	1M	✓	✓			20 A, 503 Ch	✓							✓			
Baig ¹⁴ (USA, 2010)	S	H	1M	✓				149‡		✓		✓					✓		
Barasheed ¹⁵ (Australia, 2014)	C-RCT	Tents	1W	✓	✓	✓		164; 22 tents	✓							✓			
Bryce ¹⁶ (Canada, 2008)	S	H	1WS	✓				137		✓		✓				✓			
Canin ¹⁷ (France, 2010)	C-RCT	HH	1Inf-S	✓	✓	✓		306; 105 HH	✓			✓				✓			
Chen ¹⁸ (China, 2016)	Multiple cross-over lab-based trials	Lab	NR	✓				15		✓			✓						
Chughtai ²⁰ (China, 2019)‡	Prevalence	H	2M	✓				148	✓			✓					✓		
Cowling ²² (Hong Kong, 2008)	C-RCT	HH	7M	✓	✓	✓	✓	370; 128 HH§	✓							✓			
Cowling ²¹ (Hong Kong, 2009)	C-RCT	HH	8M	✓	✓	✓	✓	1015; 322 HH§	✓							✓			
Foo ²⁴ (Singapore 2006)	S	H	2S	✓				340			✓								
Forgie ²⁵ (Canada, 2009)¶	S	ED	2M	✓	✓			80**	✓		✓						✓		
Jacobs ²⁶ (Japan, 2009)	RCT	H	2M	✓				33	✓						✓				
Kao ²⁷ (Taiwan, 2004) ††	Before-after	H	2M	✓				39		✓		✓							
Larson ¹³ (USA, 2010) with additional data from Ferng <i>et al</i> 2011 ²³	C-RCT	HH	19M	✓	✓			2708; 617 HH§	✓			✓				✓	✓		
Lee ²⁹ (Singapore, 2011)‡‡	Single arm study	Lab	NR	✓				14		✓				✓					
Lim ³⁰ (Singapore, 2006)	S	H	1Y	✓				212		✓		✓							
MacIntyre ³¹ (Australia 2009)	C-RCT	HH	2WS	✓			✓	290 A; 145 HH	✓			✓				✓			
MacIntyre ³³ (China, 2011)	C-RCT	H	3M	✓				1441; 15 H	✓		✓	✓					✓		
MacIntyre ³⁴ (China, 2013)	C-RCT	H	3M	✓				1669; 19 H	✓		✓	✓							

Continued

Table 1 Continued

First author (country, year)	Study design	Setting	Study duration	Type of participants				Type of face mask intervention†				Type of reported outcomes (adverse effects) analysed							Mask contamination
				Healthy		Sick*		Number of participants	Surgical	N95	Any	Other	Discomfort and irritation	Dyspnoea and other physiological	Misuse	Adherence	Psychological impacts	Communication impacts	
				A	Ch	A	Ch												
MacIntyre ³² (Vietnam, 2015) with additional data from Chughtai <i>et al</i> 2016 ¹⁹	C-RCT	H	5W	✓				1607; 14 H	✓		✓	✓			✓				
Martel ³⁵ (Canada, 2013)§§	Direct observation study	ED	1M	✓				115		✓	✓			✓			✓		
Nickell ³⁶ (Canada, 2004)	S	H	1M	✓				2001	✓	✓	✓			✓			✓		
Ong ³⁷ (Singapore, 2020)	S	H	2M	✓				158	✓		✓								
Or ³⁸ (Hong Kong, 2018)	Lab-based study	Lab	NR	✓				84		✓	✓						✓		
Person ³⁹ (France, 2018)	Randomised cross-over trial	NC¶	NR	✓				44	✓				✓						
Radonovich ⁴⁰ (USA, 2009)	Multiple cross-over trial	H	NC	✓				27	✓	✓	✓						✓		
Radonovich ⁴¹ (USA, 2019)	C-RCT	H	3.7Y	✓				2862	✓		✓				✓				
Rebmann ⁴² (USA, 2013)	Multiple cross-over trial	H	2D	✓				10		✓			✓						
Roberge ¹² (USA, 2012)	Cross-over	Lab	3M	✓				20	✓				✓						
Shenal ¹² (USA, 2012)	Multiple cross-over field trial	H	NR	✓				27	✓		✓		✓						
Simmernan ⁴⁵ (Thailand, 2011)	RCT	HH	16M	✓			✓	465	✓						✓				
Suess ⁴⁷ (Germany, 2012) with additional data from Suess <i>et al</i> 2011 ⁴⁶	C-RCT	HH	2Inf-S	✓			✓	111 HH	✓			✓			✓				
Thomas ⁴⁸ (USA, 2011)	NC¶¶	HB-E	NR	✓					✓		✓						✓		
Vaniak ⁴⁹ (France, 2006)	S	H	2M	✓				238 patients and 210 staff		✓				✓					
Wong ⁵⁰ (Hong Kong, 2013)	RCT	PCC	2M	✓				1031 patients and nine doctors			✓						✓		
Yeung ³⁷ (Singapore, 2020)	S	HH	1W	✓				2231 HH		✓					✓				

Continued

Table 1 Continued

First author (country, year)	Type of participants				Number of participants			Type of face mask intervention†				Type of reported outcomes (adverse effects) analysed				
	Study duration	Healthy		Sick*	A	Ch	Surgical	N95	Any	Other	Discomfort and irritation	Dyspnoea and other physiological	Psychological impacts	Communication impacts	Mask contamination	
		A	Ch													
Study design	Setting															
*Sick adults or children, with influenza, influenza-like illness or upper respiratory tract infections.																
†Only face masks arms of the included studies.																
‡Only face masks arms of the included studies.																
§Number of households that were excluded from analysis as ineligible.																
¶Number of households that were allocated.																
Participants in the waiting room of ED could be sick due to an infection.																
**Pairs of adults and children.																
***Patients with end-stage renal disease without any influenza or ILI.																
####Data reported here are for the N95 group.																
#####Two nested studies: study 1: direct observation study (data in this row)+ Study 2: survey.																
In the first part of the study, the pilot recited each word with the aircraft engine off when wearing and not wearing either the surgical face mask or one of the N95 respirators. In the second part of the study, the same procedure occurred, except that the 407-helicopter engine was running at idle.																
*****Reports three studies: pilot study 1: lab testing; pilot study 2: small clinical testing; study 3: main study, which is extracted here.																
A, healthy adults; Ch, children; C-RCT, cluster randomised controlled trial; D, days; ED, emergency departments; H, hospitals; HB-E, helicopter bell (used for helicopter emergency medical services); HH, households; Inf-S, influenza season; Lab, laboratory; M, months; N/A, not applicable; NC, not clear; NR, not reported; POC, primary care clinics; RCT, randomised controlled trial; RH, residence halls; S, survey; Sch, schools; Tel, telephone survey of home residents; W, weeks; WS, winter season; Y, year.																

*Sick adults or children, with influenza, influenza-like illness or upper respiratory tract infections.

†Only face masks arms of the included studies.

‡Authors state 159 surveys returned but 10 were excluded from analysis as ineligible.

§Number of households that were allocated.

¶Participants in the waiting room of ED could be sick due to an infection.

**Pairs of adults and children.

††Patients with end-stage renal disease without any influenza or ILI.

‡‡Data reported here are for the N95 group.

§§Two nested studies: study 1: direct observation study (data in this row); Study 2: survey.

¶¶In the first part of the study, the pilot recruited each word with the aircraft engine off when wearing and not wearing either the surgical face mask or one of the N95 respirators. In the second part of the study, the same procedure occurred, except that the 407-helicopter engine was running at idle.

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A, healthy adults; Ch, children; C-RCT, cluster randomised controlled trial; D, days; ED, emergency departments; H, hospitals; HB-E, helicopter bell (used for helicopter emergency medical services); HH, household; Inf-S, influenza season; Lab, laboratory; M, months; N/A, not applicable; NC, not clear; NR, not reported; PCC, primary care clinics; RCT, randomised controlled trial; RH, residence halls; S, survey; Sch, schools; Tel, telephone survey of home residents; W, weeks; WS, winter season; Y, year.

Studies not included in the meta-analysis

Randomised controlled trials (n=3)

One study in a residential hall setting reported similar duration of face mask wear per day in the face mask alone group versus face mask plus hand washing group (mean of 5.08 and 5.04 hours/day, respectively).¹² Another in a household setting reported that within the face mask group, there were no significant differences between individuals with ILI among contacts versus no ILI among contacts, for face mask use.¹⁷ Finally, 22 of 44 households randomised to the 'education with sanitiser and face masks' arm reported having used a mask within 48 hours of episode onset.²⁸

Observational studies (n=3)

In an elementary school setting, approximately twice as many teachers as students wore face masks.¹³ A mean compliance score with N95 use guidelines was 21.2 (on a 25-point scale) among frequent users of N95 respirators in a hospital setting.¹⁶ Another study among healthcare workers found that majority of survey respondents (91%) wore one to two masks per day (range 1–4).²⁰

Misuse

Mask misuse appears less studied than other harms and discomforts. A study of 10 nurses observed for 10 min/hour over two shifts found that they touched their face two to three times per hour, their mask five times per hour and their eyes once per 2 hours, when observed by students.⁴² In a study of health workers, 13 of the 53 who responded (25%) reported wearing masks only covering their mouth, not their nose.⁴⁹ One study conducted in two hospitals,³⁵ observed triage nurse behaviour with 118 patients with fever and cough, found that in only 18% of cases the nurses informed patients of the need to wear a mask, and in half of those, gave instruction on the need to cover both mouth and nose. A cross-sectional study evaluating the proficiency of the Singaporean public in wearing N95 masks found only 90/714 subjects passed the visual mask fit test; the most common criteria performed incorrectly were: strap placement, leaving a visible gap between the mask and skin and tightening the nose-clip.⁵¹

Discomfort and irritation

Several RCTs of specifically measured mask wear discomfort,^{17 31–33 47} but most only recorded spontaneously reported events^{12 28 34} or did not report any.^{15 21 22 26 41 45 50} A trial of household index influenza cases allocated to wear masks or no mask found the 51 allocated to masks wore them on average 3.8 hours/day and 38 (76%) reported discomfort (table 2).¹⁷ A study of healthcare workers in Beijing asked to wear masks for their full shift found 84% complained of at least one problem (table 2).²⁰ In a German household study, 65/172 participants reported problems with mask wearing, most commonly warmth, pain and shortness of breath.⁴⁷

In a trial of healthcare workers comparing surgical and N95 masks to prevent influenza, more workers found

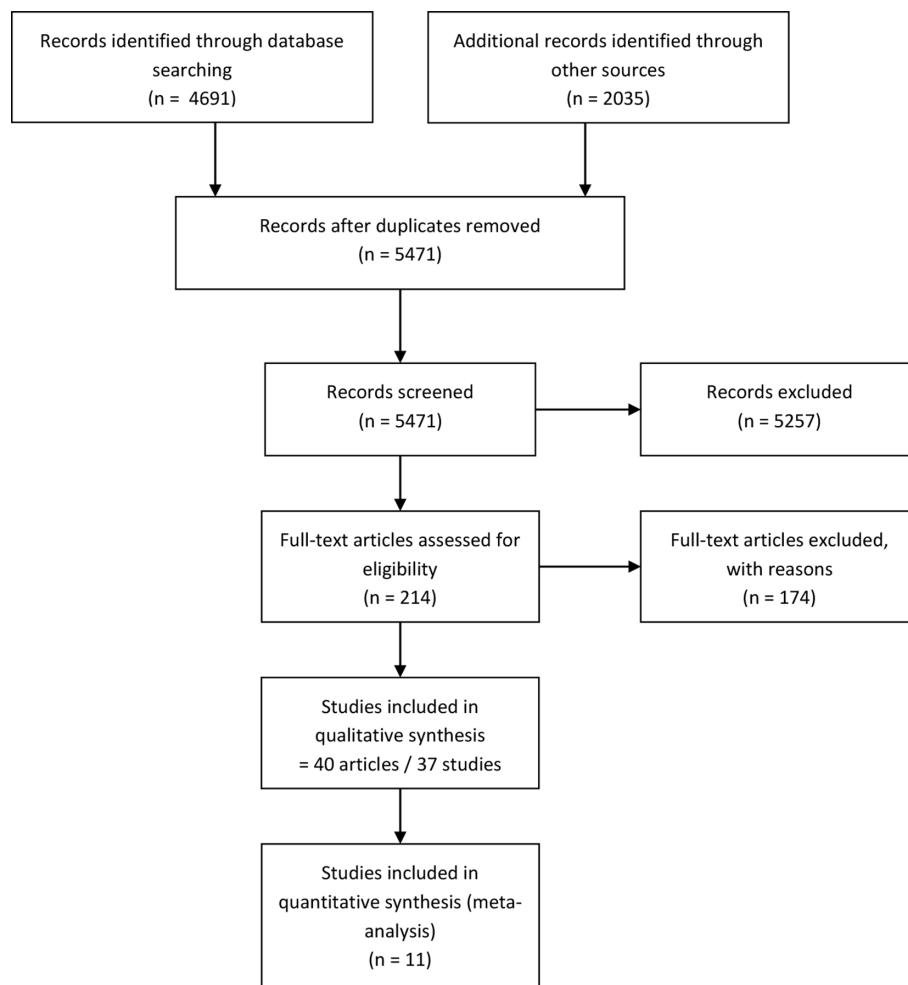


Figure 1 PRISMA flow diagram.

the N95 uncomfortable (42%) than the medical mask (10%) when worn an average of 5 hours per day,³³ with significant differences in headaches, difficulty breathing and pressure on the nose (table 2). A trial of cloth versus medical masks in healthcare workers found similar rates of discomfort.³² A community trial comparing surgical and P2 (N95) masks found >50% reporting concerns, primarily discomfort, with similar rates (15% vs 17%) across groups.³¹

Discomfort increases with duration of mask wearing. A cross-over field trial of 27 healthcare workers found increased discomfort over time; half the subjects were unwilling to wear a medical mask for the full 8-hour shift despite regularly wearing them for short periods.⁴⁴

Two surveys of healthcare staff in Singapore during the SARS epidemic assessed headache and skin reactions.^{24 30} In one survey, 79/212 (37%) reported face mask associated headaches, 26 (33%) reported headache frequency

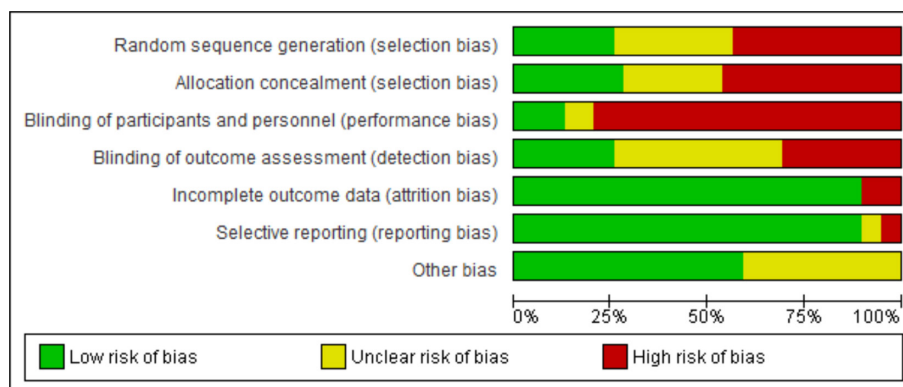


Figure 2 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

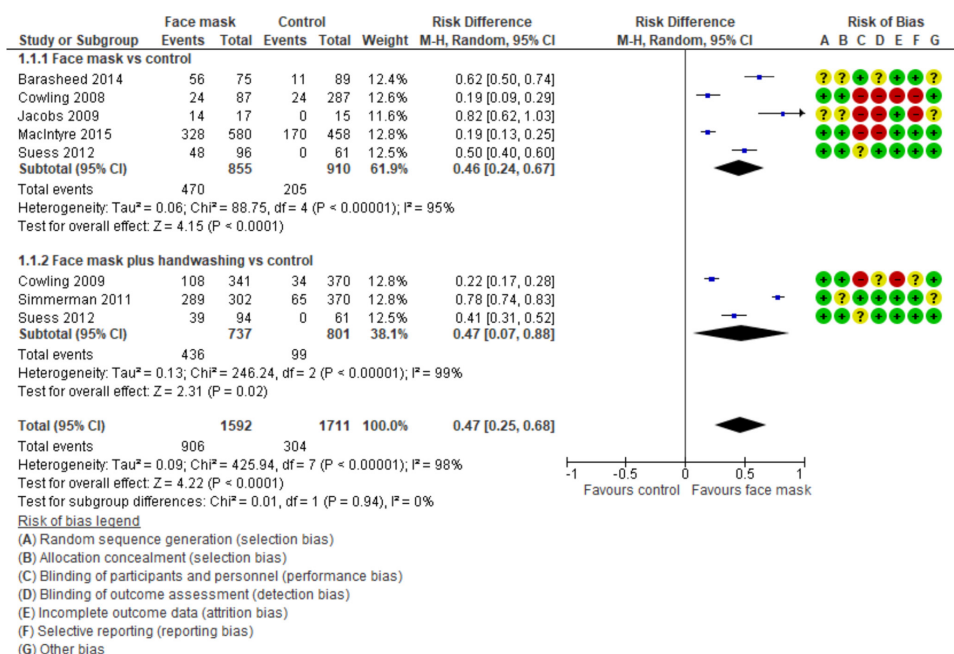


Figure 3 Comparison of adherence to face masks versus control.

exceeding six times/month and 6 had taken sick leave.³⁰ Another survey of healthcare workers in Singapore found that of the 307 staff who used masks regularly, 60% reported acne, 51% facial itch and 36% rash from N95 mask use.²⁴ A COVID-19 survey of healthcare workers in Singapore found that 128/158 (81%) developed de novo personal protective equipment (PPE)-associated headaches, increasing with duration of use (>4 hours).³⁷

One study (2×2 factorial design) examined the potential of mask fit test and training to mitigate discomfort but found no clinically or statistically important differences between arms.³⁸

Six observational studies reported either general discomfort³³ or spontaneously reported events among participants who wore face masks.^{14 16 27 35 40}

Psychological

Six studies reported on psychological impacts from wearing face masks (four RCTs and two observational).

Fear

A three-arm RCT in a household setting found significantly higher risk perception scores in the mask group

(38/60) than non-mask groups (30/60) (p<0.001); participants in the mask group were more fearful that they and their family would get sick from influenza.^{23 28}

In an observational study, children in a paediatric emergency department waiting room (n=80) were shown pictures of clinicians wearing either a surgical mask or a clear face shield; 18 children (22.5%) reported surgical masks to be more frightening due to an inability to see clinicians' faces, and 14 children (17.5%) reported face shields to be more frightening. However, 47 children (59%) reported that neither were frightening.²⁵

Stigma

In a two-arm cluster-RCT, 15 (29%) patients wearing masks reported they did not like being seen wearing a mask.¹⁷ In a three-arm RCT, more children reported disliking their parents wearing a P2 mask than a surgical mask (8/92 vs 6/94); however, the difference was not significant.³¹

Loneliness

One observational study reported on the loneliness outcome. In a survey investigating the psychosocial effects associated with working in a hospital during the

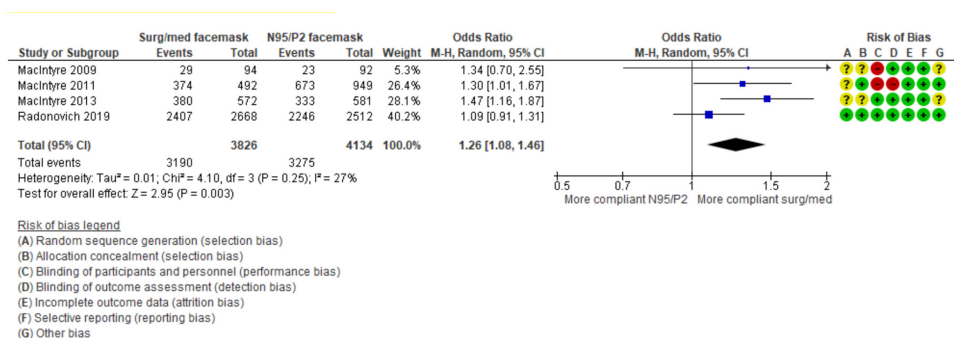


Figure 4 Comparison of adherence to surgical/medical face masks vs N95/P2 masks.

Table 2 Types of discomfort assessed in trials of face masks used to prevent viral transmission

First author, year (type of mask)	Population, number	Difficulty breathing	Facial irritation or discomfort	Headache	Other
Canini, 2010 ¹⁷ (surgical masks)	Household, 105 index cases	34%	14%	–	46% warmth
Chughtai, 2019 ²⁰ (surgical masks)	Healthcare workers, 148	12%	17%	6%	–
MacIntyre, 2011 ³³ (surgical)	Healthcare workers, 492	12%	11%	4%	–
MacIntyre, 2011 ³³ (N95)	Healthcare workers, 949	19%	52%	13%	–
MacIntyre, 2015 ³² (cloth vs medical)	Healthcare workers, 1130	18%	35%	–	–

SARS outbreak, 222 (13%) respondents reported a sense of isolation as one reason masks were perceived as bothersome.³⁶

Empathy

One RCT reported that the wearing of a face mask by doctors had a negative effect on patient perceptions of the doctors' empathy during consultations, with a mean Consultation and Relational Empathy score in the mask group of 33.93 (SD=7.65, n=514) and 34.91 (SD=7.84, n=516) in the no mask group (p=0.04).⁵⁰

Dyspnoea and other physiological consequences

Studies of physiological impacts were generally done on masks designed for dust, vapours and other non-transmission purposes; few studied surgical or N95 masks.

A French cross-over study (44 subjects) found surgical masks had no impact on 6 min walking time, but subjects had an increased sense of dyspnoea with a mask: 5.6 versus 4.6 cm on a 10 cm visual analogue scale (p<0.001),³⁹ which may come from the increased effort required. A study in 14 adults found that N95 masks increased respiratory resistance in 30 seconds of breathing by over 100%, resulting in average reduction in nasal spirometry of 37%.²⁹ A study of 20 subjects on a treadmill found the surgical masks increased respiratory rate by 1.6 breaths/min (p=0.02), heart rate by 9.5 beats/min (p<0.001) and transcutaneous CO₂ levels of 2.2 mm Hg (p<0.001).⁴³ Finally, a Chinese study of 15 subjects wearing a monitoring garment for respiratory signals found that N95 masks increased both subjective breathing resistance (from none to mild) and increased respiratory rate; the muscle activity of sternomastoid, scalene, diaphragm and abdominal; and the fatigue of scalene and intercostal.¹⁸

Communication

Nine studies (two RCT, seven observational) reported on communication difficulties while wearing face masks.

A trial comparing the use of surgical and N95 masks by healthcare workers to prevent influenza found more workers in the N95 mask group than the surgical mask group reported mask causing trouble with patient communication (8% vs 3%).³³ Another household-based

trial of 15 participants who wore a surgical mask for approximately 60 min while performing various tasks^{23 28} found that participants did not report any interference with communication while answering the phone.

In a cross-over trial of 27 healthcare workers,⁴⁰ more participants in the surgical mask group reported diminished communication acuity (visual, auditory or vocal) as the reason for discontinuing mask use before the end of an 8-hour shift (seven complaints compared with four complaints among N95 mask wearers).

Of 2001 healthcare workers in Toronto responding to a survey during the SARS outbreak, difficulty communicating (47%) and difficulty recognising people (24%) were identified as key reasons masks (surgical or N95) were perceived as being particularly bothersome.³⁶ In a survey of 149 healthcare workers,¹⁴ 41 (27.5%) of respondents reported a difficulty 'always'/'most of time' in verbally communicating with patients while wearing a mask.

In another Canadian survey (115 healthcare workers),³⁵ 26 (23%) respondents reported that wearing masks interfered with their relationships with their patients. Among 148 healthcare workers asked to wear a mask during a 6–8 hour shift, 11 (7.4%) reported trouble communicating with patients.²⁰

In a study of three participants evaluating the impact of wearing a surgical or N95 mask on radio reception, all participants were able to accurately record all pilot-recited words regardless of the type of mask worn by the pilot. However, when the aircraft engine was turned on, the accuracy decreased for the N95 mask, compared with surgical or no mask.⁴⁸

In another lab-based study, the performance or absence of fit testing prior to mask use did not affect communication, as two participants (out of 21) in each group reported ease of talking to be unsatisfactory.³⁸

Mask contamination and other issues

One concern about mask use is the potential for contamination of the mask surface and subsequent self-inoculation to the wearer's eyes or when demasking. No studies examined that directly, but one study of the healthcare workers

found on average 10% of masks had viral contamination after usage and that was higher for masks worn >6 hours (OR 7.9, 95% CI 1.01 to 61.99) or >25 patients seen (OR 5.02, 95% CI 1.35 to 18.60).²⁰ Given the rates of misuse (see Misuse section above), this contamination raises concerns about self-inoculation.

Several authors have raised concerns about ‘risk compensation’—non-adherence to other precautions because of the sense of protection—but we found no studies that quantify its extent.

DISCUSSION

We identified 37 studies reporting downsides, harms and adverse events associated with the wearing of face masks: 15 RCTs and 22 observational studies. The largest number of studies reported on the discomfort and irritation outcome (20 studies), fewest on misuse of mask (four studies), with no studies directly investigating or quantifying mask contamination or risk compensation behaviour. The only meta-analysable outcome was adherence to face mask wear (17 studies, 11 meta-analysed). Forty-seven per cent more people wore face masks in the face mask group compared with control, although the percentage of people wearing face masks in the control group was non-zero in five studies; face mask wear adherence was also significantly higher (26%) in the surgical/medical mask group than the N95/P2 group. Risk of bias was generally high for blinding of participants and personnel, and selection bias, and low for attrition and reporting biases.

This is the first systematic review to investigate the downsides of wearing face masks and forms an important step as a bridge between research and action. The review aligns with the aims of the behavioural, environmental, social and systems interventions collaboration (BESSI) and addresses important evidence gaps in the appropriate use of face masks. The review’s strength lies in its inclusion of non-randomised study designs in addition to RCTs, as trials frequently under-report or fail to report harms.⁵² Additionally, the inclusion and exclusion criteria were tested and refined on a test library of 98 references, prior to screening the full search results. The key limitation includes the hospital setting of most of the included studies: as hospital workers are accustomed to wearing masks, the conclusions may not be fully generalisable to the community. Although this varies among the studies that reported mask use in hospital setting, as there are different confounding factors that may contribute to increased reporting of irritation (eg, length of shift, air-conditioning on the wards and whether the staff were wearing the full PPE, which adds to the full discomfort). We report two differences between the protocol and the review: first, the comparison of face mask to control in the adherence outcome was reported using RD (rather than preplanned OR) to more clearly convey the differences between the two groups (OR for compliance with face mask wear

was reported for the face mask vs face mask comparison, however). Second, not having anticipated data availability, we did not prespecify a subgroup analysis of the intervention (face mask wearing) by studies that evaluated face mask wear alone and studies evaluating face mask with hand washing. Potential behavioural or cultural bias may have been introduced into the findings due to some cultural groups already being more accustomed to wearing face masks when coughing or sick. However, among our included studies, only four were conducted in the community in Asian countries, and of these studies, three reported adherence to face mask use as an issue and one study reported that 264 out of the 624 of the participants who have failed N95 fit test have used masks previously. Furthermore, the use of face masks/coverings in the various study settings compared with their use in a real-life pandemic may differ from a behavioural perspective, and this may affect findings related to adherence. However, other reported harms, such as physiological changes, may be less affected by the differences in circumstance.

Several recent systematic reviews have focused on the effectiveness of masks in preventing or reducing viral transmission; some of these reviews reported on harms in the included studies.^{8 18 42 53} However, none specifically focused on the wider set of studies examining the physiological, psychological and other adverse effects addressed in this review. The Cochrane review on physical barriers noted the impact of masks on discomfort and communication in some of the randomised trials, and its findings are consistent with this review but did not extend to studies with outcomes other than viral transmission or non-randomised study design.³

The downsides identified in this review should aid in designing strategies to mitigate problems and guide the situations where the benefits of masks might outweigh the downsides. Patient preferences for surgical masks (as indicated by the higher adherence than to the N95 masks), would suggest that the mitigation of discomforts may also increase adherence to face mask wear, and hence their effectiveness, whether for preventing transmission of the virus by the wearer (eg, surgical masks) or for preventing inhalation of viral particles in the environment (eg, N95 masks). Mitigation might be achieved by considering of the when, where and how of mask wearing (including the fitting process required for some masks like FFP and N95) as the choice of alternative would be dependent on the specific context; that is, it may not be appropriate to use surgical masks or other face masks interchangeably with respirator masks in situations where the goal is to prevent inhalation of aerosolised viral particles as they are not designed for that purpose unlike respirator masks or by mask redesign or substitution with alternatives (eg, face shields).

Potential mitigation strategies

Limiting circumstances: use of face masks should be restricted to higher risk circumstances, including

crowded, indoor spaces, where physical distancing is not possible, for example, public transport. This recommendation corresponds with suggestions by Chu *et al*, who reported that optimum face mask use in public settings could result in a large reduction in infection.⁵ Conversely, exercising outdoors is both low risk and has higher downside of wearing masks, because of the increased perceived dyspnoea.

Limiting duration of face mask wear: duration increases both discomfort and non-adherence. Duration might be decreased by demasking during breaks or scheduling mask breaks. Changing masks more often will help with adherence and the contamination risks but will increase costs and environmental problems with waste disposal, as well as lead to potential contamination/transmission risks if not performed appropriately.

Modification for specific groups: some groups are likely to have greater difficulty with mask wearing adherence and correct usage, including children, some patients with mental illnesses, those with cognitive impairment or respiratory disorders such as asthma or chronic airways disease and patients with recent facial trauma or oromaxillofacial surgery.^{54–56}

Substitution: face shields may provide an alternative to face masks, which may mitigate several of the downsides (eg, reducing the communication difficulties and breathing resistance), while also providing eye protection. However, there is little evidence on the discomforts of wearing face shields and on the degree of protection provided, as airborne particles could escape through the upward and downwards jet.^{57–58} Other innovative mask designs currently being developed require discomfort and adherence evaluations in addition to the droplet penetration.

Currently, existing research does not allow firm conclusions as there are insufficient data to quantify all of the adverse effects that might reduce the acceptability, adherence and effectiveness of face masks. Any new research on face masks should assess and report the harms and downsides, including behavioural issues (ie, risk compensation behaviour) and the psychological impact of mandated face mask wear. There is an urgent need for priority funding for high-quality research on methods and designs to mitigate downsides of face mask wearing, particularly the assessment of possible alternatives.

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Appendix 1. Summary of the different types of facemasks included in the review and their intended uses

Type of face mask/covering	Description and Intended use
Surgical mask ^{1, 2}	<ul style="list-style-type: none"> - Loose-fitting, disposable device, made in different thicknesses - Creates a physical, protective barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment i.e. splashes, sprays, large droplets or splatter. - Primarily intended to prevent the wearer from spreading respiratory droplets - Intended for single use - Does not filter or block very small particles, gases or chemicals in the air that may be transmitted by coughs, sneezes, or certain medical procedures. - Do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the mask and the face.
N95 mask ^{2, 3}	<ul style="list-style-type: none"> - Respiratory protective device designed to achieve a very close facial fit. The edges of the respirator are designed to form a seal around the nose and mouth. - Require fit-testing and must be adjusted to the face. - Intended to help reduce wearer exposure to airborne particles as well as larger droplets and protect the wearer from splashes and sprays. - Filters out very fine particles. - Commonly used in healthcare settings. - Should not be shared or reused.
Non-medical face masks/covering ⁴	<ul style="list-style-type: none"> - Cloth face coverings are only intended to help contain the wearer's respiratory droplets from being spread. - At least 2-3 layers needed to block respiratory droplets. - Not intended for use in a clinical setting or explicitly to prevent the transmission of disease between persons. - Some are reusable, and need to be washed after each use.

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Appendix 2. List of excluded face masks

- Oxygen face masks
- OxyMask
- Goldman nasal masks
- Patil-Syracuse Mask
- Ventilation masks
- non-invasive ventilation masks
- Venti-Mask
- Venturi mask
- Mechanical ventilation masks
- Facemask anaesthesia (Anaesthesia induction using face masks)
- Sports protective masks (Hockey masks)
- Diving masks, Scuba masks
- Thermoplastic masks (protective masks for irradiation fields and radiotherapy)
- Bag-valve-mask
- Laryngeal mask
- Oronasal masks
- Sleep masks
- N95 masks with valves (as it does not reduce the spread of virus transmission)

Appendix 3. Database search strings

Searches conducted 18 May 2020:

PubMed

("Masks/adverse effects"[MAJR])

OR

((Masks[Mesh] OR "Respiratory protective devices"[Mesh] OR Facemask[tiab] OR Facemasks[tiab] OR Mask[tiab] OR Masks[tiab] OR Faceshield[tiab] OR Faceshields[tiab] OR Goggles[tiab] OR "Face shield"[tiab] OR "Face shields"[tiab] OR Visors[tiab] OR "Face covering"[tiab]))

AND

("Adverse effects"[sh] OR "Adverse effect"[tiab] OR "Adverse effects"[tiab] OR "Adversely affect"[tiab] OR "Adverse event"[tiab] OR "Adverse events"[tiab] OR Discomfort[tiab] OR Fatigue[tiab] OR Pain[tiab] OR "Difficulty breathing"[tiab] OR "Breathing difficulty"[tiab] OR "Shortness of breath"[tiab] OR "Risk compensation"[tiab] OR Fomite[tiab] OR Fomites[tiab] OR Dislike[tiab] OR "Physiological impacts"[tiab] OR "Physiological impact"[tiab] OR Sweating[tiab] OR Irritation[tiab] OR "Psychological reactions"[tiab] OR Fear[tiab] OR Communication[tiab] OR "Deaf persons"[tiab] OR Lip-reading[tiab] OR "Lip reading"[tiab] OR Vitiligo[tiab] OR Humidity[tiab] OR "Face dermatitis"[tiab] OR Acne[tiab] OR Redness[tiab] OR Ulcer[tiab] OR "Speech understanding"[tiab] OR "Pinching of skin"[tiab] OR "Moisture buildup"[tiab] OR "Facial warmth"[tiab])

AND

(Relieve[tiab] OR Attitudes[tiab] OR Induced[tiab] OR Modified[tiab] OR Decreased[tiab] OR Decrease[tiab] OR Associated[tiab] OR Impair[tiab] OR Reduce[tiab] OR Reducing[tiab] OR Reduced[tiab] OR Duration[tiab])

AND

("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR randomized[tiab] OR randomised[tiab] OR placebo[tiab] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR "Epidemiologic Studies"[Mesh] OR "case-control studies"[Mesh] OR "Cohort Studies"[Mesh] OR "case control"[tiab] OR Cohort[tiab] OR "Follow up"[tiab] OR Observational[tiab] OR Longitudinal[tiab] OR Prospective[tiab] OR Retrospective[tiab] OR "cross sectional"[tiab] OR "Cross-Sectional Studies"[Mesh] OR Evaluated[tiab] OR Impact[tiab] OR Analysis[tiab] OR Statistics[tiab] OR Data[tiab] OR "statistics and numerical data"[sh] OR "epidemiology"[sh] OR Etiology[sh] OR Effect[tiab] OR Effects[tiab] OR Affect[tiab]))

NOT

("Continuous Positive Airway Pressure"[Mesh] OR "Positive Airway Pressure"[tiab] OR CPAP[tiab] OR "Laryngeal Masks"[Mesh] OR "Intubation, Intratracheal"[Mesh] OR "Oxygen masks"[tiab] OR

"Oxygen mask"[tiab] OR OxyMask[tiab] OR "Nasal masks"[tiab] OR "Patil-Syracuse Mask"[tiab] OR "Ventilation masks"[tiab] OR "Venti-Mask"[tiab] OR "Venturi mask"[tiab] OR "Diving masks"[tiab] OR "Thermoplastic masks"[tiab] OR Bag-valve-mask[tiab] OR "Laryngeal mask"[tiab] OR "Laryngeal masks"[tiab] OR "Oronasal masks"[tiab] OR "Sleep mask"[tiab] OR Editorial[pt] OR Letter[pt] OR "Case reports"[pt])

NOT

(Animals[Mesh] not (Animals[Mesh] and Humans[Mesh]))

OR

(Masks[Mesh] OR "Respiratory protective devices"[Mesh] OR Facemask[tiab] OR Facemasks[tiab] OR Mask[tiab] OR Masks[tiab] OR Faceshield[tiab] OR Faceshields[tiab] OR Goggles[tiab] OR "Face shield"[tiab] OR "Face shields"[tiab] OR Visors[tiab] OR "Face covering"[tiab])

AND

("Respiratory Tract Infections"[Mesh] OR Influenza[tiab] OR "Respiratory Tract Diseases"[Mesh] OR Influenzas[tiab] OR "Influenza-like"[tiab] OR ILI[tiab] OR "common cold"[tiab] OR colds[tiab] OR coryza[tiab] OR coronavirus[Mesh] OR "sars virus"[Mesh] OR coronavirus[tiab] OR Coronaviruses[tiab] OR "coronavirus infections"[Mesh] OR "severe acute respiratory syndrome"[Mesh] OR "severe acute respiratory syndrome"[tiab] OR "severe acute respiratory syndromes"[tiab] OR sars[tiab] OR "respiratory syncytial viruses"[Mesh] OR "respiratory syncytial virus, human"[Mesh] OR "Respiratory Syncytial Virus Infections"[Mesh] OR "respiratory syncytial virus"[tiab] OR "respiratory syncytial viruses"[tiab] OR rsv[tiab] OR parainfluenza[tiab] OR "Respiratory illness"[tiab] OR ((Transmission[tiab]) AND (Coughing[tiab] OR Sneezing[tiab])) OR ((respiratory[tiab] AND Tract[tiab]) AND (infection[tiab] OR Infections[tiab] OR illness[tiab])) OR "Communicable Disease Control"[Mesh] OR "Disease Outbreaks"[Mesh] OR "Disease Transmission, Infectious"[Mesh] OR "Infection Control"[Mesh] OR Transmission[sh] OR "Communicable Disease Control"[tiab] OR "Secondary transmission"[tiab] OR ((Reduced[tiab] OR Reduce[tiab] OR Reduction[tiab] OR Reducing[tiab] OR Lower[tiab]) AND (Incidence[tiab] OR Occurrence[tiab] OR Transmission[tiab] OR Secondary[tiab])) OR Physiological[tiab])

AND

("Adverse effects"[sh] OR "Adverse effect"[tiab] OR "Adverse effects"[tiab] OR "Adverse event"[tiab] OR "Adverse events"[tiab] OR "Index cases"[tiab] OR "Attack rates"[tiab] OR ((Reduce[tiab] OR Reduction[tiab]) AND (Rate[tiab] OR Rates[tiab])) OR Perception[tiab] OR Prevent[tiab] OR Adherence[tiab])

AND

("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR randomized[tiab] OR randomised[tiab] OR placebo[tiab] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR "Epidemiologic Studies"[Mesh] OR "case-control studies"[Mesh] OR "Cohort Studies"[Mesh] OR "case control"[tiab] OR Cohort[tiab] OR "Follow up"[tiab] OR Observational[tiab] OR Longitudinal[tiab] OR Prospective[tiab] OR retrospective[tiab] OR "cross sectional"[tiab] OR "Cross-

Sectional Studies"[Mesh] OR Evaluated[tiab] OR Impact[tiab] OR Analysis[tiab] OR Statistics[tiab] OR Data[tiab] OR "statistics and numerical data"[sh] OR "epidemiology"[sh])

NOT

("Continuous Positive Airway Pressure"[Mesh] OR "Positive Airway Pressure"[tiab] OR CPAP[tiab] OR "Laryngeal Masks"[Mesh] OR "Intubation, Intratracheal"[Mesh] OR "Oxygen masks"[tiab] OR "Oxygen mask"[tiab] OR OxyMask[tiab] OR "Goldman nasal masks"[tiab] OR "Patil-Syracuse Mask"[tiab] OR "Ventilation masks"[tiab] OR "Venti-Mask"[tiab] OR "Venturi mask"[tiab] OR "Hockey mask"[tiab] OR "Diving masks"[tiab] OR "Thermoplastic masks"[tiab] OR Bag-valve-mask[tiab] OR "Laryngeal mask"[tiab] OR "Laryngeal masks"[tiab] OR "Oronasal masks"[tiab] OR "Sleep mask"[tiab] OR "Case Reports"[pt])

NOT

(Animals[Mesh] not (Animals[Mesh] and Humans[Mesh]))

Cochrane CENTRAL

(([mh Masks/AE])

OR

(([mh Masks] OR [mh "Respiratory protective devices"] OR Facemask:ti,ab OR Facemasks:ti,ab OR Mask:ti,ab OR Masks:ti,ab OR Faceshield:ti,ab OR Faceshields:ti,ab OR Goggles:ti,ab OR "Face shield":ti,ab OR "Face shields":ti,ab OR Visors:ti,ab OR "Face covering":ti,ab)

AND

("Adverse effect":ti,ab OR "Adverse effects":ti,ab OR "Adversely affect":ti,ab OR "Adverse event":ti,ab OR "Adverse events":ti,ab OR Discomfort:ti,ab OR Fatigue:ti,ab OR Pain:ti,ab OR "Difficulty breathing":ti,ab OR "Breathing difficulty":ti,ab OR "Shortness of breath":ti,ab OR "Risk compensation":ti,ab OR Fomite:ti,ab OR Fomites:ti,ab OR Dislike:ti,ab OR "Physiological impacts":ti,ab OR "Physiological impact":ti,ab OR Sweating:ti,ab OR Irritation:ti,ab OR "Psychological reactions":ti,ab OR Fear:ti,ab OR Communication:ti,ab OR "Deaf persons":ti,ab OR "Lip reading":ti,ab OR Vitiligo:ti,ab OR Humidity:ti,ab OR "Glasses misting" OR "Face dermatitis":ti,ab OR Acne:ti,ab OR Redness:ti,ab OR Ulcer:ti,ab OR "Speech understanding":ti,ab OR "Pinching of skin":ti,ab OR "Moisture buildup":ti,ab OR "Facial warmth":ti,ab)

AND

(Relieve:ti,ab OR Attitudes:ti,ab OR Induced:ti,ab OR Modified:ti,ab OR Decreased:ti,ab OR Decrease:ti,ab OR Associated:ti,ab OR Impair:ti,ab OR Reduce:ti,ab OR Reducing:ti,ab OR Reduced:ti,ab OR Duration:ti,ab)))

NOT

([mh "Continuous Positive Airway Pressure"] OR "Positive Airway Pressure":ti,ab OR CPAP:ti,ab OR [mh "Laryngeal Masks"] OR [mh "Intubation, Intratracheal"] OR "Oxygen masks":ti,ab OR "Oxygen mask":ti,ab OR OxyMask:ti,ab OR "Nasal masks":ti,ab OR "Patil Syracuse Mask":ti,ab OR "Ventilation masks":ti,ab OR "Venti Mask":ti,ab OR "Venturi mask":ti,ab OR "Hockey mask":ti,ab OR "Diving masks":ti,ab OR "Thermoplastic masks":ti,ab OR "Bag valve mask":ti,ab OR "Laryngeal mask":ti,ab OR "Laryngeal masks":ti,ab OR "Oronasal masks":ti,ab OR "Sleep mask":ti,ab)

OR

([mh Masks] OR [mh "Respiratory protective devices"] OR Facemask:ti,ab OR Facemasks:ti,ab OR Mask:ti,ab OR Masks:ti,ab OR Faceshield:ti,ab OR Faceshields:ti,ab OR Goggles:ti,ab OR "Face shield":ti,ab OR "Face shields":ti,ab OR Visors:ti,ab OR "Face covering":ti,ab)

AND

([mh "Respiratory Tract Infections"] OR Influenza:ti,ab OR [mh "Respiratory Tract Diseases"] OR Influenzas:ti,ab OR ILI:ti,ab OR "common cold":ti,ab OR colds:ti,ab OR coryza:ti,ab OR [mh coronavirus] OR [mh "sars virus"] OR coronavirus:ti,ab OR Coronaviruses:ti,ab OR [mh "coronavirus infections"] OR [mh "severe acute respiratory syndrome"] OR "severe acute respiratory syndrome":ti,ab OR "severe acute respiratory syndromes":ti,ab OR sars:ti,ab OR [mh "respiratory syncytial viruses"] OR [mh "respiratory syncytial virus, human"] OR [mh "Respiratory Syncytial Virus Infections"] OR "respiratory syncytial virus":ti,ab OR "respiratory syncytial viruses":ti,ab OR rsv:ti,ab OR parainfluenza:ti,ab OR "Respiratory illness":ti,ab OR ((Transmission:ti,ab) AND (Coughing:ti,ab OR Sneezing:ti,ab)) OR ((respiratory:ti,ab AND Tract:ti,ab) AND (infection:ti,ab OR Infections:ti,ab OR illness:ti,ab)) OR [mh "Communicable Disease Control"] OR [mh "Disease Outbreaks"] OR [mh "Disease Transmission, Infectious"] OR [mh "Infection Control"] OR "Communicable Disease Control":ti,ab OR "Secondary transmission":ti,ab OR ((Reduced:ti,ab OR Reduce:ti,ab OR Reduction:ti,ab OR Reducing:ti,ab OR Lower:ti,ab) AND (Incidence:ti,ab OR Occurrence:ti,ab OR Transmission:ti,ab OR Secondary:ti,ab)) OR Physiological:ti,ab)

AND

("Adverse effect":ti,ab OR "Adverse effects":ti,ab OR "Adverse event":ti,ab OR "Adverse events":ti,ab OR "Index cases":ti,ab OR "Attack rates":ti,ab OR ((Reduce:ti,ab OR Reduction:ti,ab) AND (Rate:ti,ab OR Rates:ti,ab)) OR Perception:ti,ab OR Prevent:ti,ab OR Adherence:ti,ab)

NOT

([mh "Continuous Positive Airway Pressure"] OR "Positive Airway Pressure":ti,ab OR CPAP:ti,ab OR [mh "Laryngeal Masks"] OR [mh "Intubation, Intratracheal"] OR "Oxygen masks":ti,ab OR "Oxygen mask":ti,ab OR OxyMask:ti,ab OR "Goldman nasal masks":ti,ab OR "Patil-Syracuse Mask":ti,ab OR "Ventilation masks":ti,ab OR "Venti Mask":ti,ab OR "Venturi mask":ti,ab OR "Hockey mask":ti,ab OR "Diving masks":ti,ab OR "Thermoplastic masks":ti,ab OR "Bag valve mask":ti,ab OR "Laryngeal mask":ti,ab OR "Laryngeal masks":ti,ab OR "Oronasal masks":ti,ab OR "Sleep mask":ti,ab)

Embase

('Masks'/exp OR 'Respiratory protective devices'/exp OR Facemask:ti,ab OR Facemasks:ti,ab OR Mask:ti,ab OR Masks:ti,ab OR Faceshield:ti,ab OR Faceshields:ti,ab OR Goggles:ti,ab OR "Face shield":ti,ab OR "Face shields":ti,ab OR Visors:ti,ab OR "Face covering":ti,ab)

AND

("Adverse effect":ti,ab OR "Adverse effects":ti,ab OR "Adversely affect":ti,ab OR "Adverse event":ti,ab OR "Adverse events":ti,ab OR Discomfort:ti,ab OR Fatigue:ti,ab OR Pain:ti,ab OR "Difficulty breathing":ti,ab OR "Breathing difficulty":ti,ab OR "Shortness of breath":ti,ab OR "Risk compensation":ti,ab OR Fomite:ti,ab OR Fomites:ti,ab OR Dislike:ti,ab OR "Physiological impacts":ti,ab OR "Physiological impact":ti,ab OR Sweating:ti,ab OR Irritation:ti,ab OR "Psychological reactions":ti,ab OR Fear:ti,ab OR Communication:ti,ab OR "Deaf persons":ti,ab OR Lip-reading:ti,ab OR "Lip reading":ti,ab OR Vitiligo:ti,ab OR Humidity:ti,ab OR "Glasses misting" OR "Face dermatitis":ti,ab OR Acne:ti,ab OR Redness:ti,ab OR Ulcer:ti,ab OR "Speech understanding":ti,ab OR "Pinching of skin":ti,ab OR "Moisture buildup":ti,ab OR "Facial warmth":ti,ab)

AND

(Relieve:ti,ab OR Attitudes:ti,ab OR Induced:ti,ab OR Modified:ti,ab OR Decreased:ti,ab OR Decrease:ti,ab OR Associated:ti,ab OR Impair:ti,ab OR Reduce:ti,ab OR Reducing:ti,ab OR Reduced:ti,ab OR Duration:ti,ab)

AND

("randomized controlled trial":it OR "controlled clinical trial":it OR randomized:ti,ab OR randomised:ti,ab OR placebo:ti,ab OR randomly:ti,ab OR trial:ti,ab OR groups:ti,ab OR 'Epidemiology'/exp OR 'case control study'/exp OR 'cohort analysis'/exp OR "case control":ti,ab OR Cohort:ti,ab OR "Follow up":ti,ab OR Observational:ti,ab OR Longitudinal:ti,ab OR Prospective:ti,ab OR retrospective:ti,ab OR "cross sectional":ti,ab OR 'cross-sectional study'/exp OR Evaluated:ti,ab OR Impact:ti,ab OR Analysis:ti,ab OR Statistics:ti,ab OR Data:ti,ab OR Etiology:ti,ab OR Effect:ti,ab OR Effects:ti,ab OR Affect:ti,ab)

NOT

('positive end expiratory pressure'/exp OR "Positive Airway Pressure":ti,ab OR CPAP:ti,ab OR 'laryngeal mask'/exp OR 'endotracheal intubation'/exp OR "Oxygen masks":ti,ab OR "Oxygen mask":ti,ab OR OxyMask:ti,ab OR "Goldman nasal masks":ti,ab OR "Patil-Syracuse Mask":ti,ab OR "Ventilation masks":ti,ab OR Venti-Mask:ti,ab OR "Venturi mask":ti,ab OR "Hockey mask":ti,ab OR "Diving masks":ti,ab OR "Thermoplastic masks":ti,ab OR Bag-valve-mask:ti,ab OR "Laryngeal mask":ti,ab OR "Laryngeal masks":ti,ab OR "Oronasal masks":ti,ab OR "Sleep mask":ti,ab OR 'letter'/exp OR 'editorial'/exp OR 'case report'/exp)

NOT

('Animal'/exp NOT ('Animal'/exp AND 'Human'/exp))

AND

[embase]/lim

OR

('Mask'/exp OR 'gas mask'/exp OR Facemask:ti,ab OR Facemasks:ti,ab OR Mask:ti,ab OR Masks:ti,ab OR Faceshield:ti,ab OR Faceshields:ti,ab OR Goggles:ti,ab OR "Face shield":ti,ab OR "Face shields":ti,ab OR Visors:ti,ab OR "Face covering":ti,ab)

AND

('respiratory tract infection'/exp OR Influenza:ti,ab OR 'respiratory tract disease'/exp OR Influenzas:ti,ab OR Influenza-like:ti,ab OR ILI:ti,ab OR "common cold":ti,ab OR colds:ti,ab OR coryza:ti,ab OR 'Coronavirinae'/exp OR 'SARS coronavirus'/exp OR coronavirus:ti,ab OR Coronaviruses:ti,ab OR 'Coronavirus infection'/exp OR 'severe acute respiratory syndrome'/exp OR "severe acute respiratory syndrome":ti,ab OR "severe acute respiratory syndromes":ti,ab OR sars:ti,ab OR 'Pneumovirus'/exp OR 'Human respiratory syncytial virus'/exp OR 'respiratory syncytial virus infection'/exp OR "respiratory syncytial virus":ti,ab OR "respiratory syncytial viruses":ti,ab OR rsv:ti,ab OR parainfluenza:ti,ab OR "Respiratory illness":ti,ab OR ((Transmission:ti,ab) AND (Coughing:ti,ab OR Sneezing:ti,ab)) OR ((respiratory:ti,ab AND Tract:ti,ab) AND (infection:ti,ab OR Infections:ti,ab OR illness:ti,ab)) OR 'communicable disease control'/exp OR 'epidemic'/exp OR 'disease transmission'/exp OR 'Infection Control'/exp OR "Communicable Disease Control":ti,ab OR "Secondary transmission":ti,ab OR ((Reduced:ti,ab OR Reduce:ti,ab OR Reduction:ti,ab OR Reducing:ti,ab OR Lower:ti,ab) AND (Incidence:ti,ab OR Occurrence:ti,ab OR Transmission:ti,ab OR Secondary:ti,ab)) OR Physiological:ti,ab)

AND

('adverse event'/exp OR "Adverse effect":ti,ab OR "Adverse effects":ti,ab OR "Adverse event":ti,ab OR "Adverse events":ti,ab OR "Index cases":ti,ab OR "Attack rates":ti,ab OR ((Reduce:ti,ab OR Reduction:ti,ab) AND (Rate:ti,ab OR Rates:ti,ab)) OR Perception:ti,ab OR Prevent:ti,ab OR Adherence:ti,ab)

AND

("randomized controlled trial":it OR "controlled clinical trial":it OR randomized:ti,ab OR randomised:ti,ab OR placebo:ti,ab OR randomly:ti,ab OR trial:ti,ab OR groups:ti,ab OR 'Epidemiology'/exp OR 'case control study'/exp OR 'cohort analysis'/exp OR "case control":ti,ab OR Cohort:ti,ab OR "Follow up":ti,ab OR Observational:ti,ab OR Longitudinal:ti,ab OR Prospective:ti,ab OR retrospective:ti,ab OR "cross sectional":ti,ab OR 'cross-sectional study'/exp OR Evaluated:ti,ab OR Impact:ti,ab OR Analysis:ti,ab OR Statistics:ti,ab OR Data:ti,ab)

NOT

('positive end expiratory pressure'/exp OR "Positive Airway Pressure":ti,ab OR CPAP:ti,ab OR 'laryngeal mask'/exp OR 'endotracheal intubation'/exp OR "Oxygen masks":ti,ab OR "Oxygen mask":ti,ab OR OxyMask:ti,ab OR "Goldman nasal masks":ti,ab OR "Patil-Syracuse Mask":ti,ab OR "Ventilation masks":ti,ab OR Venti-Mask:ti,ab OR "Venturi mask":ti,ab OR "Hockey mask":ti,ab OR "Diving masks":ti,ab OR "Thermoplastic masks":ti,ab OR Bag-valve-mask:ti,ab OR "Laryngeal

mask":ti,ab OR "Laryngeal masks":ti,ab OR "Oronasal masks":ti,ab OR "Sleep mask":ti,ab OR "Case Reports":it)

NOT

('Animal'/exp NOT ('Animal'/exp AND 'Human'/exp))

AND

[embase]/lim

Europe PMC

<https://europepmc.org/search?query=%28TITLE%3A%22masks%22%20AND%20%28%222019-nCoV%22%20OR%20%222019nCoV%22%20OR%20%22COVID-19%22%20OR%20%22SARS-CoV-2%22%20OR%20%28%22wuhan%22%20AND%20%22coronavirus%22%29%20OR%20%22Coronaviruses%22%20OR%20%22Corona%20virus%22%20OR%20%22corona-virus%22%20OR%20%22corona%20viruses%22%20OR%20%22coronaviruses%22%20OR%20%22SARS-CoV%22%20OR%20%22Orthocoronavirinae%22%20OR%20%22MERS-CoV%22%20OR%20%22Severe%20Acute%20Respiratory%20Syndrome%22%20OR%20%22Middle%20East%20Respiratory%20Syndrome%22%20OR%20%28%22SARS%22%20AND%20%22virus%22%29%20OR%20%22soluble%20ACE2%22%20OR%20%28%22ACE2%22%20AND%20%22virus%22%29%20OR%20%28%22ARDS%22%20AND%20%22virus%22%29%29%29%20AND%20%28SRC%3APP%29&page=1>

Appendix 4. List of excluded studies**Excluded studies from database search**

No.	Reference	Reason for exclusion
1.	Ahmad, E. F., et al. (2001). "The effect of wearing the veil by Saudi ladies on the occurrence of respiratory diseases." <i>J Asthma</i> 38(5): 423-426.	Study type
2.	Ahmad, I., et al. (2017). "Assessment of knowledge, practice and barrier in use of facemask among university students." <i>Pakistan Journal of Medical and Health Sciences</i> 11(4): 1657-1658.	Reported outcomes
3.	Aiello, A. E., et al. (2010). "A randomized intervention trial of mask use and hand hygiene to reduce seasonal influenza-like illness and influenza infections among young adults in a university setting." <i>International Journal of Infectious Diseases</i> 14: e320.	Duplicate
4.	Aiello, A. E., et al. (2010). "Mask use, hand hygiene, and seasonal influenza-like illness among young adults: a randomized intervention trial." <i>J Infect Dis</i> 201(4): 491-498.	No extractable data
5.	Akyuz, N., et al. (2014). "How and how much do endoscopy professionals protect themselves against infection?" <i>Int J Surg</i> 12(7): 720-724.	Reported outcomes
6.	Albarrak, A. I., et al. (2019). "Middle East Respiratory Syndrome (MERS): Comparing the knowledge, attitude and practices of different health care workers." <i>J Infect Public Health</i> .	Reported outcomes
7.	AlGhamri, A. A., et al. (2013). "The effects of wearing respirators on human fine motor, visual, and cognitive performance." <i>Ergonomics</i> 56(5): 791-802.	Intervention
8.	Allsopp, J., et al. (1997). "Survey of the use of personal protective equipment and prevalence of work related symptoms among dental staff." <i>Occup Environ Med</i> 54(2): 125-134.	Reported outcomes
9.	Alqahtani, A. S., et al. (2016). "Exploring barriers to and facilitators of preventive measures against infectious diseases among Australian Hajj pilgrims: cross-sectional studies before and after Hajj." <i>Int J Infect Dis</i> 47: 53-59.	No extractable data
10.	Alsarheed, M. (2011). "Children's Perception of Their Dentists." <i>Eur J Dent</i> 5(2): 186-190.	Study type
11.	Aydin, O., et al. (24 April 2020). "Performance of fabrics for home-	Reported

	made masks against spread of respiratory infection through droplets: a quantitative mechanistic study." PREPRINT (Version 1 - 2020.04.19.20071779), Available at: medRxiv: https://doi.org/10.1101/2020.04.19.20071779 .	outcomes
12.	Badin, A. (1969). "[The surgeon's fatigue and discomfort behind the mask]." <i>Gynaecologia</i> 167(5): 430-433.	Study type
13.	Bansal, S., et al. (2009). "Respirator physiological effects under simulated work conditions." <i>J Occup Environ Hyg</i> 6(4): 221-227.	Intervention
14.	Beuvelet, M., et al. (2017). "Healthcare workers' perception towards the systematic use of mask during a seasonal influenza outbreak in a French University Hospital: A descriptive study." <i>Antimicrobial Resistance and Infection Control</i> 6.	Unable to access full text
15.	Bhoirul, B., et al. (2019). "A review of non-glove personal protective equipment-related occupational dermatoses reported to EPIDERM between 1993 and 2013." <i>Contact Dermatitis</i> 80(4): 217-221.	Study type
16.	Bischoff, W., et al. (2017). "Evaluation of a novel powered air-purifying respirator (PAPR) vs. a N95 respirator mask for the protection against influenza in a human exposure model." <i>Open Forum Infectious Diseases</i> 4: S168.	Reported outcomes
17.	Brandt, C., et al. (2011). "Attitudes of influenza-vaccinated health care workers toward masks to prevent nosocomial transmission of influenza." <i>Influenza Other Respir Viruses</i> 5(1): 61-66.	Study type
18.	Buitrago, F. (2010). "Hygienic measures and barriers are effective strategies to prevent the transmission of viral infections." <i>FMC Formacion Medica Continuada en Atencion Primaria</i> 17(5): 361.	Study type
19.	Caretti, D. M. and P. D. Gardner (1999). "Respirator fit factor performance while sweating." <i>American Industrial Hygiene Association Journal</i> 60(1): 84-88.	Intervention
20.	Chan, E. Y., et al. (2015). "Knowledge, attitudes, and practices of Hong Kong population towards human A/H7N9 influenza pandemic preparedness, China, 2014." <i>BMC Public Health</i> 15: 943.	Reported outcomes
21.	Chan, M. F., et al. (2008). "Investigating the knowledge, attitudes and practice patterns of operating room staff towards standard and transmission-based precautions: results of a cluster analysis." <i>J Clin Nurs</i> 17(8): 1051-1062.	Reported outcomes
22.	Chan, M. T., et al. (2013). "Mask ventilation and dispersion of exhaled air." <i>Am J Respir Crit Care Med</i> 187(7): e12-14.	Study type

23.	Cherrie, J. W., et al. (2019). "In-mask temperature and humidity can validate respirator wear-time and indicate lung health status." <i>J Expo Sci Environ Epidemiol</i> 29(4): 578-583.	Intervention
24.	Chung, P. K., et al. (2017). "The process by which perceived autonomy support predicts motivation, intention, and behavior for seasonal influenza prevention in Hong Kong older adults." <i>BMC Public Health</i> 18(1): 65.	Study type
25.	Coca, A., et al. (2017). "Physiological Evaluation of Personal Protective Ensembles Recommended for Use in West Africa." <i>Disaster Med Public Health Prep</i> 11(5): 580-586.	Intervention
26.	Collyer, S. and P. J. Davis (2006). "Effect of facemask use on respiratory patterns of women in speech and singing." <i>J Speech Lang Hear Res</i> 49(2): 412-423.	Reported outcomes
27.	Condon, B. J. and T. Sinha (2010). "Who is that masked person: the use of face masks on Mexico City public transportation during the Influenza A (H1N1) outbreak." <i>Health Policy</i> 95(1): 50-56.	Reported outcomes
28.	Davies, A., et al. (2013). "Testing the efficacy of homemade masks: would they protect in an influenza pandemic?" <i>Disaster Med Public Health Prep</i> 7(4): 413-418.	Reported outcomes
29.	Davis, P. J., et al. (2007). "A survey of Alberta physicians' use of and attitudes toward face masks and face shields in the operating room setting." <i>Am J Infect Control</i> 35(7): 455-459.	Reported outcomes
30.	Del Ferraro, S., et al. (2018). "Hot environment: Effects of a power assisted filtering device incorporating a full face mask on newton manikin thermophysiological response." <i>Occupational and Environmental Medicine</i> 75: A503-A504.	Study type
31.	Del Ferraro, S., et al. (2017). "Thermophysiological response of Newton manikin equipped with power-assisted filtering device incorporating a full-face mask in hot environment." <i>Int J Hyperthermia</i> 33(7): 717-723.	Population
32.	Deris, Z. Z., et al. (2010). "The prevalence of acute respiratory symptoms and role of protective measures among Malaysian Hajj pilgrims." <i>Journal of Travel Medicine</i> 17(2): 82-88.	Study type
33.	Derrick, J. L. and C. D. Gomersall (2005). "Protecting healthcare staff from severe acute respiratory syndrome: filtration capacity of multiple surgical masks." <i>J Hosp Infect</i> 59(4): 365-368.	Reported outcomes
34.	Ding, S., et al. (1998). "[Heat strain for personnel wearing three levels	Intervention

	of protective ensembles at moderate and heavy workloads]." Wei Sheng Yan Jiu 27(6): 361-364.	
35.	DiLeo T, Roberge RJ, Kim JH. Effect of wearing an N95 filtering facepiece respirator on superomedial orbital infrared indirect brain temperature measurements. J Clin Monit Comput. 2017;31(1):67-73.	Reported outcomes
36.	Dong, J. and Y. Chen (2010). "Impact of the bag exchange procedure on risk of peritonitis." Perit Dial Int 30(4): 440-447.	Reported outcomes
37.	Ellison, I. R. T. (2009). "Surgical masks or N95 respirators for the flu?" Medicine Today 10(12): 69-70.	Reported outcomes
38.	Emanuel, R., et al. (2017). "A study of special care dental patient preference toward choice of mask and visor use by dental clinicians." Spec Care Dentist 37(4): 164-167.	Reported outcomes
39.	Fabian, P., et al. (2011). "Influenza virus aerosols in human exhaled breath: Particle size, culturability, and effect of surgical masks." Epidemiology 22(1): S51.	Reported outcomes
40.	Field, M. H., et al. (2020). "Hydrocolloid dressing strip over bridge of nose to relieve pain and pressure from Filtered Face Piece (FFP) masks during the coronavirus (COVID-19) pandemic." Ann R Coll Surg Engl 102(5): 394-396.	Study type
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43.	Fox, S. H. and A. B. DuBois (1993). "The effect of evaporative cooling of respiratory protective devices on skin temperature, thermal sensation, and comfort." Am Ind Hyg Assoc J 54(12): 705-710.	Intervention
44.	Ganczak, M. and Z. Szych (2007). "Surgical nurses and compliance with personal protective equipment." J Hosp Infect 66(4): 346-351.	Reported outcomes
45.	Gu, J., et al. (2015). "Preventive behaviors and mental distress in response to H1N1 among university students in Guangzhou, China." Asia Pac J Public Health 27(2): Np1867-1879.	Reported outcomes
46.	Guo, Y. P., et al. (2008). "Evaluation on masks with exhaust valves and with exhaust holes from physiological and subjective responses." J	Intervention

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47.	Gwosdow, A. R., et al. (1989). "Effect of thermal conditions on the acceptability of respiratory protective devices on humans at rest." <i>Am Ind Hyg Assoc J</i> 50(4): 188-195.	Intervention
48.	Hassaniazad, M., et al. (2016). "Preventive measures for Crimean-Congo hemorrhagic fever in healthcare workers; how high is the chance of transmission?" <i>Acta Medica Mediterranea</i> 32: 2017-1024.	Reported outcomes
49.	Harber, P., et al. (1989). "Relationship of subjective tolerance of respirator loads to physiologic effects and psychophysical load sensitivity." <i>J Occup Med</i> 31(8): 681-686.	Intervention
50.	Hardis, K. E., et al. (1983). "Correlation of qualitative and quantitative results from testing respirator fit." <i>Am Ind Hyg Assoc J</i> 44(2): 78-87.	Intervention
51.	Hickey, J., et al. (2014). "Pandemic preparedness: perceptions of vulnerable migrants in Thailand towards WHO-recommended non-pharmaceutical interventions: a cross-sectional study." <i>BMC Public Health</i> 14: 665.	Reported outcomes
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53.	Ho, R. C., et al. (2014). "Impact of 2013 south Asian haze crisis: study of physical and psychological symptoms and perceived dangerousness of pollution level." <i>BMC Psychiatry</i> 14: 81.	Reported outcomes
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58.	James, R., et al. (1984). "Effects of respirators under heat/work conditions." <i>Am Ind Hyg Assoc J</i> 45(6): 399-404.	Intervention

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60.	Johnson, A. T., et al. (2000). "Effect of external dead volume on performance while wearing a respirator." <i>Aihaj</i> 61(5): 678-684.	Intervention
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63.	Kim, J. H., et al. (2015). "Effect of wearing an N95 respirator on infrared tympanic membrane temperature measurements." <i>J Clin Monit Comput</i> 29(6): 691-695.	Reported outcomes
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67.	Latheef, F., et al. (2015). "Personal protective equipment-associated dermatoses reported to EPIDERM: A 20-year review." <i>British Journal of Dermatology</i> 173: 172-173.	Duplicate
68.	Lau, J. T., et al. (2003). "Monitoring community responses to the SARS epidemic in Hong Kong: from day 10 to day 62." <i>J Epidemiol Community Health</i> 57(11): 864-870.	Reported outcomes
69.	Leung, N. H., et al. (06 March 2020). "Respiratory Virus Shedding in Exhaled Breath and Efficacy of Face Masks." PREPRINT (Version 1), Available at: Research Square [https://doi.org/10.21203/rs.3.rs-16836/v1],.	Reported outcomes
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76.	Lonnroth, E. C. and H. Shahnava (1998). "Adverse health reactions in skin, eyes, and respiratory tract among dental personnel in Sweden." Swed Dent J 22(1): 33-45.	Reported outcomes
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78.	Lunding, S., et al. (1998). "[Poor compliance with universal precautions among Danish physicians]." Ugeskr Laeger 160(12): 1789-1793.	Reported outcomes
79.	Lutz, M., et al. (2019). "Physiological effects of a spit sock." Am J Emerg Med 37(2): 291-293.	Intervention
80.	Ma, X., et al. (2014). "Knowledge, attitudes and practices relating to influenza A(H7N9) risk among live poultry traders in Guangzhou City, China." BMC Infect Dis 14: 554.	Reported outcomes
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83.	Maschmeyer, G., et al. (2009). "A prospective, randomised study on the use of well-fitting masks for prevention of invasive aspergillosis in	Intervention

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85.	Mauritzson-Sandberg, E. (1995). "An evaluation of respiratory protective devices used in children's evacuation." <i>Ergonomics</i> 38(4): 707-713.	Purpose of study
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90.	Moser, A., et al. (2015). "Rates and determinants of vaccination against seasonal and pandemic influenza in Swiss prehospital emergency medical services workers." <i>Praxis</i> 104: 142.	Study type
91.	Moser, A., et al. (2016). "Vaccination Against Seasonal or Pandemic Influenza in Emergency Medical Services." <i>Prehosp Disaster Med</i> 31(2): 155-162.	Study type
92.	Motoyama, Y. L., et al. (2016). "Airflow-Restricting Mask Reduces Acute Performance in Resistance Exercise." <i>Sports (Basel)</i> 4(4).	Intervention
93.	Nichol, K., et al. (2008). "The individual, environmental, and organizational factors that influence nurses' use of facial protection to prevent occupational transmission of communicable respiratory illness in acute care hospitals." <i>Am J Infect Control</i> 36(7): 481-487.	Study type
94.	Nichol, K., et al. (2013). "Behind the mask: Determinants of nurse's adherence to facial protective equipment." <i>Am J Infect Control</i> 41(1): 8-13.	Study type
95.	Nielsen, R., et al. (1987). "The effect of temperature and humidity levels in a protective mask on user acceptability during exercise." <i>Am Ind Hyg Assoc J</i> 48(7): 639-645.	Intervention

96.	Palmiero, A. J., et al. (2016). "Speech intelligibility assessment of protective facemasks and air-purifying respirators." <i>J Occup Environ Hyg</i> 13(12): 960-968.	Study type
97.	Parveen, S. N. A., et al. (2018). "Identifying acceptable and feasible infection control interventions for nipah encephalitis outbreaks in bangladesh." <i>American Journal of Infection Control</i> 46(6): S24.	Study type
98.	Peponis, T., et al. (2017). "Trauma team utilization of universal precautions: if you see something, say something." <i>Eur J Trauma Emerg Surg</i> 43(1): 145-150.	Reported outcomes
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101.	Radonovich, L., et al. (2018). "Results of the respiratory protection effectiveness clinical trial (respect)." <i>Open Forum Infectious Diseases</i> 5: S51.	Duplicate
102.	Ramirez, J. A. and P. T. O'Shaughnessy (2016). "The effect of simulated air conditions on N95 filtering facepiece respirators performance." <i>J Occup Environ Hyg</i> 13(7): 491-500.	Study type
103.	Raven, P. B., et al. (1977). "Maximal stress test performance while wearing a self-contained breathing apparatus." <i>J Occup Med</i> 19(12): 802-806.	Intervention
104.	Rengasamy, S. and B. C. Eimer (2013). "N95-companion measurement of cout/cin ratios for two n95 filtering facepiece respirators and one surgical mask." <i>J Occup Environ Hyg</i> 10(10): 527-532.	Population
105.	Roberge, R. (2011). "Facemask use by children during infectious disease outbreaks." <i>Biosecur Bioterror</i> 9(3): 225-231.	Study type
106.	Roberge, R. J., et al. (2010). "Surgical mask placement over N95 filtering facepiece respirators: physiological effects on healthcare workers." <i>Respirology</i> 15(3): 516-521.	Intervention
107.	Roberge, R. J., et al. (2010). "Reusable elastomeric air-purifying respirators: physiologic impact on health care workers." <i>Am J Infect Control</i> 38(5): 381-386.	Intervention

108.	Rozzi, T., et al. (2012). "Pilot study of aromatic hydrocarbon adsorption characteristics of disposable filtering facepiece respirators that contain activated carbon." <i>J Occup Environ Hyg</i> 9(11): 624-629.	Purpose of study
109.	van der Sande, M., et al. (2008). "Professional and home-made face masks reduce exposure to respiratory infections among the general population." <i>PLoS ONE</i> 3(7): e2618.	Reported outcomes
110.	Santos, P. B., et al. (2013). "Adherence to biosafety practices by nursing staff in the face of situations of occupational risk." <i>Antimicrobial Resistance and Infection Control</i> 2.	Unable to access full text
111.	Schmitt, C. H. (2004). "Secrets behind the mask." <i>US News World Rep</i> 137(4): 37-41.	Study type
112.	Seliga, R., et al. (1991). "Effect of work load and respirator wear on postural stability, heart rate, and perceived exertion." <i>Am Ind Hyg Assoc J</i> 52(10): 417-422.	Intervention
113.	Seng, M., et al. (2018). "Comfort and exertion while using filtering facepiece respirators with exhalation valve and an active venting system among male military personnel." <i>Singapore Med J</i> 59(6): 327-334.	Purpose of study
114.	Smith, C. L., et al. (2013). "Carbon dioxide rebreathing in respiratory protective devices: influence of speech and work rate in full-face masks." <i>Ergonomics</i> 56(5): 781-790.	Intervention
115.	Sokol, K. A., et al. (2016). "Masks for prevention of respiratory viruses on the BMT unit: results of a quality initiative." <i>Transpl Infect Dis</i> 18(6): 965-967.	Reported outcomes
116.	Stebbins, S., et al. (2009). "Using nonpharmaceutical interventions to prevent influenza transmission in elementary school children: parent and teacher perspectives." <i>J Public Health Manag Pract</i> 15(2): 112-117.	Reported outcomes
117.	Stockwell, R. E., et al. (2018). "Prolonged wear of face masks prevents the release of pseudomonas aeruginosa aerosols during coughing in people with cystic fibrosis." <i>Pediatric Pulmonology</i> 53: 269.	Unable to access full text
118.	Strauch, A. L., et al. (2016). "Assessing the efficacy of tabs on filtering facepiece respirator straps to increase proper doffing techniques while reducing contact transmission of pathogens." <i>J Occup Environ Hyg</i> 13(10): 794-801.	Intervention
119.	Sullivan, K. (1993). "Surgical face masks: protection of self or patient?" <i>N Z Dent J</i> 89(398): 137.	Study type

120.	Suruda, A., et al. (2003). "Fatal injuries in the United States involving respirators, 1984-1995." <i>Appl Occup Environ Hyg</i> 18(4): 289-292.	Study type
121.	Tak, C. N., et al. (2009). "Preventing healthcare workers from acquiring influenza." <i>Infection Control and Hospital Epidemiology</i> 30(3): 292-295.	Reported outcomes
122.	Tan, K. T. and M. W. Greaves (2004). "N95 acne." <i>Int J Dermatol</i> 43(7): 522-523.	Study type
123.	Tang, C. S. and C. Y. Wong (2004). "Factors influencing the wearing of facemasks to prevent the severe acute respiratory syndrome among adult Chinese in Hong Kong." <i>Prev Med</i> 39(6): 1187-1193.	Reported outcomes
124.	Tataris, K., et al. (2010). "Patient attitudes and compliance while wearing surgical masks to prevent disease transmission." <i>Academic Emergency Medicine</i> 17: S58.	Unable to access full text
125.	Vanjak, D., et al. (2006). "[Cases of pertussis among healthcare workers in a maternity ward: management of a health alert]." <i>Med Mal Infect</i> 36(3): 151-156.	Duplicate reference
126.	Vijaya, K., et al. (2005). "Behaviour of Singaporeans during the SARS outbreak: The impact of anxiety and public satisfaction with media information." <i>International Journal of Health Promotion and Education</i> 43(1): 17-22.	Reported outcomes
127.	Wong, S. Y., et al. (2012). "Primary care physicians' response to pandemic influenza in Hong Kong: a mixed quantitative and qualitative study." <i>Int J Infect Dis</i> 16(9): e687-691.	Reported outcomes
128.	Yang, P., et al. (2011). "Mask-wearing and respiratory infection in healthcare workers in Beijing, China." <i>Braz J Infect Dis</i> 15(2): 102-108.	Study type

Excluded studies identified from Forward & Backward citation analysis

129.	Barratt, R., et al. (2019). "Enablers of, and barriers to, optimal glove and mask use for routine care in the emergency department: an ethnographic study of Australian clinicians." <i>Australasian Emergency Care</i> .	Study type
130.	Caretti, D. M. and L. C. Strickler (2003). "Speech intelligibility during respirator wear: Influences of respirator speech diaphragm size and background noise." <i>American Industrial Hygiene Association Journal</i> 64(6): 846-850.	Intervention
131.	Chughtai, A. A., et al. (2015). "Practices around the use of masks and	Reported

	respirators among hospital health care workers in 3 diverse populations." American Journal of Infection Control 43(10): 1116-1118.	outcomes
132.	Enerson, D. M., et al. (1967). "Heat and moisture trapping beneath surgical face masks: a consideration of factors affecting the surgeon's discomfort and performance." Surgery 62(6): 1007-1016.	Reported outcomes
133.	Goh, D. Y. T., et al. (2019). "A randomised clinical trial to evaluate the safety, fit, comfort of a novel N95 mask in children." Scientific Reports 9(1).	Purpose of study
134.	Harber P, Bansal S, Santiago S, et al. Multidomain subjective response to respirator use during simulated work. Journal of Occupational and Environmental Medicine. 2009;51(1):38-45.	Reported outcomes
135.	Harber, P., et al. (2010). "Respirator physiologic impact in persons with mild respiratory disease." Journal of Occupational and Environmental Medicine 52(2): 155-162.	Intervention
136.	Harber, P., et al. (2011). "Respirator impact on work task performance." Journal of Occupational and Environmental Medicine 53(1): 22-26.	Reported outcomes
137.	Honarbakhsh, M., et al. (2018). "Knowledge, perceptions and practices of healthcare workers regarding the use of respiratory protection equipment at Iran hospitals." Journal of Infection Prevention 19(1): 29-36.	Reported outcomes
138.	Jacobs, J. L., et al. (2009). "Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: A randomized controlled trial." American Journal of Infection Control 37(5): 417-419.	Duplicate
139.	Jones, J. G. (1991). "The physiological cost of wearing a disposable respirator." American Industrial Hygiene Association Journal 52(6): 219-225.	Intervention
140.	Kim, J. H., et al. (2013). "Pulmonary and heart rate responses to wearing N95 filtering facepiece respirators." American Journal of Infection Control 41(1): 24-27.	Reported outcomes
141.	Kim, J. H., et al. (2015). "Pressure drop of filtering facepiece respirators: How low should we go?" International Journal of Occupational Medicine and Environmental Health 28(1): 71-80.	Intervention
142.	Kim, J. H., et al. (2016). "Physiologic and fit factor profiles of N95 and P100 filtering facepiece respirators for use in hot, humid	Reported

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143.	Lim, E. C. H., et al. (2007). "Headaches and the N95 face-mask amongst healthcare providers [2]." Acta Neurologica Scandinavica 116(1): 73.	Duplicate
144.	Li Y, Tokura H, Guo YP, et al. Effects of wearing N95 and surgical facemasks on heart rate, thermal stress and subjective sensations. International Archives of Occupational and Environmental Health. 2005;78(6):501-509.	No extractable data
145.	Lin, Y. C. and C. P. Chen (2019). "Thermoregulation and thermal sensation in response to wearing tight-fitting respirators and exercising in hot-and-humid indoor environment." Building and Environment 160.	Intervention
146.	Locatelli, S. M., et al. (2014). "Health care workers' reported discomfort while wearing filtering face-piece respirators." Workplace Health and Safety 62(9): 362-368.	Reported outcomes
147.	Luximon, Y., et al. (2016). "Time dependent infrared thermographic evaluation of facemasks." Work 54(4): 825-835.	Reported outcomes
148.	MacIntyre, C. R., et al. (2014). "Efficacy of face masks and respirators in preventing upper respiratory tract bacterial colonization and co-infection in hospital healthcare workers." Preventive Medicine 62: 1-7.	Reported outcomes
149.	MacIntyre, C. R., et al. (2013). "A randomized clinical trial of three options for N95 respirators and medical masks in health workers." American Journal of Respiratory and Critical Care Medicine 187(9): 960-966.	Duplicate
150.	Mauritzson-Sandberg, E. V. A. (1991). "Psychological effects on prolonged use of respiratory protective devices in children." Ergonomics 34(3): 313-319.	Reported outcomes
151.	McDiarmid, M., et al. (2020). "N95 Respirators vs Medical Masks in Outpatient Settings." JAMA - Journal of the American Medical Association 323(8): 789.	Study type
152.	Morishima, M., et al. (2014). "Experiences and problems with hygiene masks reported by japanese hay fever sufferers." International Journal of Clothing Science and Technology 26(4): 262-273.	Intervention
153.	Morishima, M., et al. (2017). "Problems related to mask use in hay fever sufferers by repeated surveys." International Journal of Clothing Science and Technology 29(1): 123-134.	Purpose of study

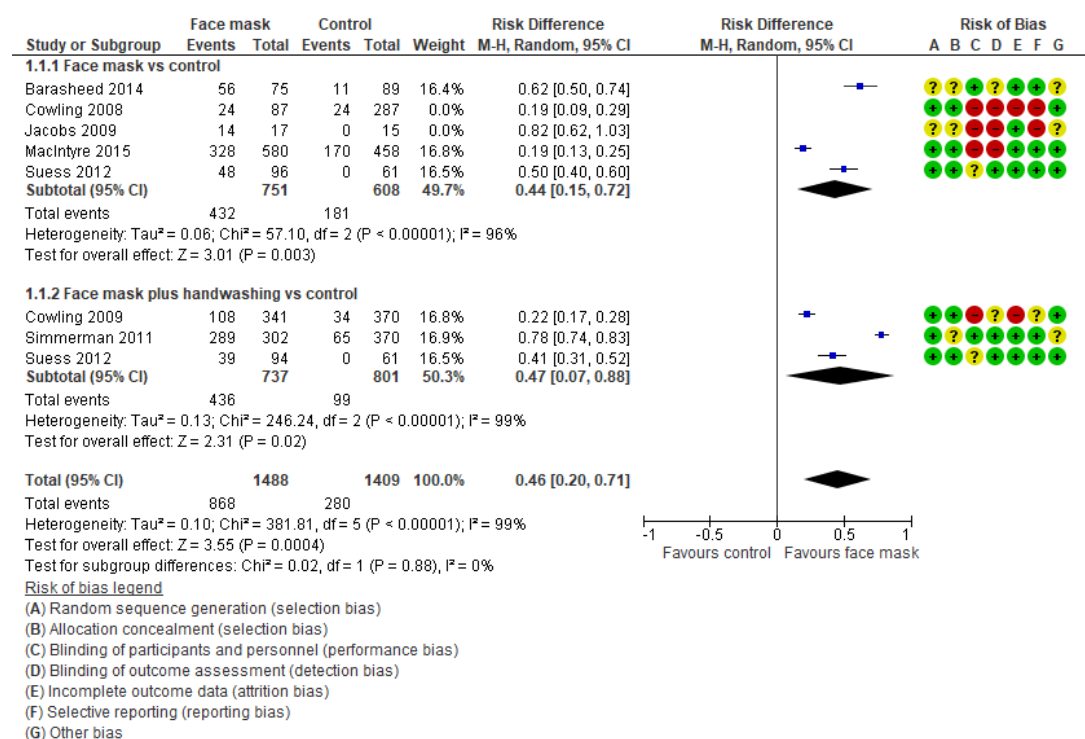
154.	Ong, J. J. Y., et al. (2020). "Headaches Associated With Personal Protective Equipment – A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19." <i>Headache</i> 60(5): 864-877.	Duplicate
155.	Phin NF, Rylands AJ, Allan J, Edwards C, Enstone JE, Nguyen-Van-Tam JS. Personal protective equipment in an influenza pandemic: a UK simulation exercise. <i>Journal of Hospital Infection</i> . 2009;71(1):15-21.	Study design
156.	Radonovich Jr, L. J., et al. (2010). "Diminished speech intelligibility associated with certain types of respirators worn by healthcare workers." <i>Journal of Occupational and Environmental Hygiene</i> 7(1): 63-70.	Intervention
157.	Radonovich, L. J., et al. (2019). "A tolerability assessment of new respiratory protective devices developed for health care personnel: A randomized simulated clinical study." <i>PLoS ONE</i> 14(1).	No extractable data
158.	Roberge, R., et al. (2012). "Thermal burden of N95 filtering facepiece respirators." <i>Annals of Occupational Hygiene</i> 56(7): 808-814.	Reported outcomes
159.	Roberge, R. J. (2008). "Effect of surgical masks worn concurrently over N95 filtering facepiece respirators: Extended service life versus increased user burden." <i>Journal of Public Health Management and Practice</i> 14(2): E19-E26.	Study type
160.	Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ. Physiological impact of the n95 filtering facepiece respirator on healthcare workers. <i>Respiratory Care</i> . 2010;55(5):569-577.	Intervention
161.	Roberge, R. J., et al. (2010). "Effect of exhaled moisture on breathing resistance of N95 filtering facepiece respirators." <i>Annals of Occupational Hygiene</i> 54(6): 671-677.	Study type
162.	Roberge, R. J., et al. (2012). "N95 filtering facepiece respirator deadspace temperature and humidity." <i>Journal of Occupational and Environmental Hygiene</i> 9(3): 166-171.	Reported outcomes
163.	Roberge, R. J., et al. (2013). "Impact of low filter resistances on subjective and physiological responses to filtering facepiece respirators." <i>PLoS ONE</i> 8(12).	Intervention
164.	Roberge RJ, Kim JH, Powell JB. N95 respirator use during advanced pregnancy. <i>American Journal of Infection Control</i> . 2014;42(10):1097-1100.	No extractable data
165.	Sakaguchi, H., et al. (2010). "Maintenance of influenza virus infectivity on the surfaces of personal protective equipment and clothing used in healthcare settings." <i>Environmental Health and Preventive Medicine</i>	Purpose of study

	15(6): 344-349.	
166.	Shi, J., et al. (2017). "Cardiovascular benefits of wearing particulate-filtering respirators: A randomized crossover trial." <i>Environmental Health Perspectives</i> 125(2): 175-180.	Purpose of study
167.	Shigayeva, A., et al. (2007). "Factors associated with critical-care healthcare workers' adherence to recommended barrier precautions during the Toronto severe acute respiratory syndrome outbreak." <i>Infection Control and Hospital Epidemiology</i> 28(11): 1275-1283.	No extractable data
168.	Skaria, S. D. and G. C. Smaldone (2014). "Respiratory source Control using surgical masks with nanofiber media." <i>Annals of Occupational Hygiene</i> 58(6): 771-781.	Purpose of study
169.	Tamura, E., et al. (2013). "Effect of pharmacists wearing a mask on patient consultation intention." <i>Yakugaku Zasshi</i> 133(6): 737-745.	Study type
170.	Tong, P. S. Y., et al. (2015). "Respiratory consequences of N95-type Mask usage in pregnant healthcare workers-A controlled clinical study." <i>Antimicrobial Resistance and Infection Control</i> 4(1).	Intervention
171.	Turnberg, W., et al. (2009). "Personal healthcare worker (HCW) and work-site characteristics that affect HCWs' use of respiratory-infection control measures in ambulatory healthcare settings." <i>Infection Control and Hospital Epidemiology</i> 30(1): 47-52.	Reported outcomes
172.	Wada, K., et al. (2012). "Wearing face masks in public during the influenza season may reflect other positive hygiene practices in Japan." <i>BMC Public Health</i> 12(1).	Reported outcomes
173.	Wu, S., et al. (2011). "Anxiety during respirator use: Comparison of two respirator types." <i>Journal of Occupational and Environmental Hygiene</i> 8(3): 123-128.	Study type
174.	Yip, W. L., et al. (2005). "The effect of wearing a face mask on body temperature." <i>Hong Kong Journal of Emergency Medicine</i> 12(1): 23-27.	Reported outcomes

Appendix 5. Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Aiello 2012	+	+	+	+	+	+	+
Allison 2010	+	+	+	+	+	+	+
Baig 2010	+	+	?	+	+	+	?
Barasheed 2014	?	?	+	?	+	+	?
Bryce 2008	+	+	?	+	+	+	+
Canini 2010	+	+	+	+	+	+	+
Chan 2015	+	+	?	+	+	+	+
Chen 2016	?	?	+	?	+	+	?
Chughtai 2019	+	+	?	+	+	+	+
Cowling 2008	+	+	+	+	+	+	+
Cowling 2009	+	+	?	+	?	+	+
DiLeo 2017	+	+	+	+	+	+	+
Foo 2006	+	+	?	+	+	+	?
Forgie 2009	+	+	?	+	+	+	?
Jacobs 2009	?	?	+	+	+	+	?
Kao 2004	+	+	+	+	+	+	?
Larson 2010	?	?	?	+	?	?	?
Lee 2011	+	+	+	+	+	+	+
Lim 2006	+	+	?	+	+	+	?
MacIntyre 2009	?	?	+	+	+	+	?
MacIntyre 2011	?	+	+	+	+	+	+
MacIntyre 2013	?	?	+	+	+	+	?
MacIntyre 2015	+	+	+	+	+	+	+
Martel 2013	+	+	?	+	+	+	+
Nickell 2004	+	+	?	+	+	+	+
Ong 2020	+	+	?	+	+	+	+
Or 2018	+	+	+	+	+	+	?
Person 2018	?	?	?	?	+	+	+
Radonovich 2009	?	?	+	+	+	+	+
Radonovich 2019	+	+	+	+	+	+	+
Rebmann 2013	?	?	+	+	+	+	?
Roberge 2012	?	+	+	+	+	+	+
Shenal 2012	+	+	?	+	+	+	?
Simmerman 2011	+	?	+	+	+	+	?
Suess 2012	+	+	?	+	+	+	+
Thomas 2011	+	+	?	+	+	+	?
Vanjak 2006	+	+	?	+	+	+	+
Wong 2013	+	+	+	+	+	+	+
Yeung 2020	?	+	+	+	+	+	+

Appendix 5. Figure 4. Analysis with studies rated at high risk of bias in more than 2 domains excluded



Appendix 5. Figure 5. Analysis with studies sub-grouped by setting (community setting, hospital setting)

